

AACT Now - AI Accelerates Data-driven Answers Today for Better Treatments Tomorrow

Navis Bio Develops AI-powered Tool that Streamlines Access to CTTI's Aggregate Analysis of ClinicalTrials.gov (AACT) Database

SUMMARY

What happens when you combine a vast clinical trial database with the speed of artificial intelligence (AI)? You get answers to your toughest research questions almost as fast as you can type them.

Navis-Bio is a company based in the U.S. and Switzerland focused on transforming clinical trials by providing advanced AI tools that help researchers analyze complex data that can strategically identify therapeutic targets, improve research study design, and accelerate the discovery process. When designing their AI interface solution, the Navis Bio team of technical experts knew that their tool would need access to an up-to-date, expansive source of clinical trial data that could provide the types of answers researchers need. However, building and maintaining a database of that magnitude would require an extensive amount of labor and significantly delay the launch of their solution. Fortunately, the team discovered CTTI's [Aggregate Analysis of ClinicalTrials.gov \(AACT\) database](#), a structured, relational database developed to store and analyze research study data.

GOAL(S)

As pharmaceutical industry veterans, the founders of Navis Bio were well aware of the challenges research partners face. Limited time and resources often made it difficult for planning teams to incorporate answers to pre-clinical and clinical trial questions that feed strategic decisions like which compounds to study and how best to design a research study. While large amounts of evidence-based data is publicly available on places like [ClinicalTrials.gov](#), many research collaborators felt that the only way to properly pinpoint and evaluate the type of data they needed required a team of analysts and a lot of time.

Navis Bio identified a recurring need to give researchers quick insights by collecting and analyzing cross-sections of data from completed and pending clinical trials including study treatments, patient populations, inclusion criteria, and biomarker strategies. By having faster access to this information, research partners could answer questions and draw meaningful conclusions that would allow them to build a more comprehensive strategy earlier in the development phase. This would help to eliminate the redundancies that can occur when multiple sponsors study the same compounds and modalities. Armed with this information, research sponsors could improve resource allocation, create differentiated products, and facilitate better innovation.

By harnessing AI technology, the Navis Bio team knew they could empower research partners by streamlining their ability to access and analyze vital information. They set out to develop a set of advanced data analysis tools that would allow trial collaborators to identify therapeutic targets, accelerate discovery, facilitate breakthroughs, improve patient outcomes, and transform clinical trials.

CHALLENGES

Prior to founding their company in 2024, the Navis Bio team knew that AI technology had the power to bridge the gap in data accessibility that would help researchers and organizations make evidence-based decisions faster and easier. By developing the right tools, they could democratize access to clinical trial information, reduce inefficiencies, and enable data-driven strategies.

However, developing a robust AI interface was only half the battle. The tool would still need to integrate with a source of up-to-date, expansive clinical trial data in order to provide the answers and results that researchers need. Since all AI models can become overloaded when asked to parse large amounts of data, connecting directly to a source such as [ClinicalTrials.gov](#) would not work well.

In order to facilitate AI interactions, the data would need to be provided in a highly structured format designed to provide accurate answers to specific questions. To build and maintain a database of that magnitude and scale would require the team to invest an extensive amount of time and ongoing labor. Since creating this type of database would significantly delay the development of their AI solution, the Navis Bio team searched for an existing source of clinical trial data structured in a way an AI tool could access and understand.

SOLUTION(S)

The Navis Bio team learned about CTTI's [AACT](#) database while attending an AI workshop and immediately realized it would provide the perfect source of clinical trial data they needed to integrate with their AI solution. AACT is a cloud-based, relational database that provides public access to information from every study registered on [ClinicalTrials.gov](#). The database collects vast amounts of research data and puts it literally at your fingertips.

AACT is refreshed daily and contains detailed study information including protocol and summary results data which enables researchers to conduct more extensive and efficient analyses. Researchers can download and analyze clinical trial data using open-source software tools to track development trends, analyze trial patterns, and generate insights about therapeutic landscapes.

Once researchers access the database, they can learn more about how the structured data tables are organized using the [AACT database schema](#). They can download AACT data or access it through the cloud and analyze it using open-source software tools like PostgreSQL, Ruby on Rails, and Tableau Public. For researchers who want to learn more, CTTI has provided [resources](#) that include a [guide to using the AACT database](#) and a [data dictionary](#) containing detailed information on all AACT data elements and corresponding Medical Subject Heading definitions from the National Library of Medicine.

CTTI's AACT database gave the Navis Bio team a thorough source of structured clinical trial information essential for the development of their AI tool. By creating an AI interface that could communicate with AACT, Navis Bio could make it easier for users to explore the database.

TAKING ACTION

Once they discovered AACT, the Navis Bio team got to work developing their AI tool. Starting with the AACT database gave the team a comprehensive and detailed overview of clinical trials and the structured format was vital to developing their AI-driven analyses.

The team believed that starting with human trial data would be crucial for reverse translation. By integrating large language models (LLMs) with AACT, they could allow users to ask human-level questions, which the AI could then translate into the Structured Query Language (SQL) needed to retrieve information from the database. AACT served as a central repository of data, allowing the team to later add information from other places such as published literature, abstracts, and other sources to provide a broader overview of the clinical trial landscape.

To build the AI interface, the team leveraged the Model Context Protocol (MCP) developed by [Anthropic](#). By creating a specialized MCP server that can be used in Anthropic's next-generation AI tool, [Claude](#), or other compatible software, the Navis Bio team had a standardized way to connect an LLM application with AACT and other external sources.

Anthropic's Claude is capable of a wide variety of conversational and text processing tasks while maintaining a high degree of reliability and predictability. These features gave the team's AI tool an easy-to-use chat interface that simplified queries for users. To further streamline the process, the team developed a series of system prompts to condense and summarize information. By guiding users to ask more precise questions, they enabled the AI to navigate the extensive AACT database more efficiently.

The result was an AI interface and chat feature that allowed users to easily retrieve complex clinical trial data from AACT that could help them track development trends, identify key findings, analyze clinical trial patterns, and generate insights into many therapeutic conditions.

IMPACT

AACT provided the Navis Bio team with a structured and comprehensive source of clinical trial information enabling them to develop AI tools designed to spark data-driven decision-making in all areas of research development. The team's open-source AI tool is designed to support translational research and biomedical data analysis by categorizing information from various sources including AACT.

The easy-to-use interface made clinical trial information more accessible by democratizing access to this information. While working with research partners, the Navis Bio team learned that some were previously unaware of the AACT database. Others were familiar with it but lacked the technical expertise to develop the SQL queries needed to access it. For both groups, streamlining and simplifying the query process opened new opportunities to collect and analyze important strategic data. Making this data available also supported smaller biotech companies who had limited resources by giving them the advantage of faster, evidence-based decision making.

Now, Navis Bio also offers research partners an advanced consultation option for more tailored solutions that provide in-depth strategic and competitive information. This service helps partners to overcome barriers by providing evidence-based answers to specific questions needed to fuel strategy and boost success.

Navis Bio's scalable and easy-to-use AI tools give partners and key decision makers insight into areas like inclusion and exclusion criteria, recruitment, and precision medicine biomarkers that can greatly impact the success of a trial. Sometimes a potential treatment option can fail a clinical trial simply because the wrong patient population was selected. Using multimodal data in these scenarios can help to ensure a better match between a patient population and the potential treatment being studied.

For all partners, improved data access provides some of the most significant benefits during the early-stage clinical trial planning process. By using the most current data to make well-informed decisions, they can avoid errors, improve efficiency and, over time, provide patients with more innovative treatment solutions. Because better data is important at all study stages, Navis Bio is working to integrate their tools throughout the entire development pipeline to facilitate better informed decisions at every step of the clinical trial continuum.

ADVICE

The Navis Bio team emphasized the importance of overcoming initial barriers to using tools like AACT and AI. "Many people hesitate because they overestimate how difficult, complicated, or time consuming it is to access this data and they underestimate the value it provides," says Navis Bio's chief technical officer. "However, there are many accessible resources, like AACT, that actually help you to save time and improve your decision-making. With the help of our AI tools, you can even access this data in a meeting or during an important discussion. The tools are also useful if you are just curious about a general question or want to learn more about a research topic. By tapping into the educational value these databases provide, partners receive a wealth of accessible information to guide their clinical development decisions. The efficiencies gained are well worth the initial time investment since these tools will help to improve decision-making capabilities, avoid costly mistakes, and streamline clinical trial development processes."

As an early-stage startup, Navis Bio's initial goal to build an interface that simplifies the process to ask research-related questions was an opportunity to significantly improve translational research and clinical trial outcomes.

Next, they plan to augment their existing tools by incorporating additional data from press releases and other publicly available sources to give a more comprehensive picture of the clinical trials ecosystem. Another goal is to share more

open-source tools that benefit the broader community, like dashboards that provide additional landscape information. They also plan to develop more predictive AI models that can do things like learn from past experience or calculate the probability of a trial's success which would make the development process more efficient.


Long term, the Navis Bio team is certain that the use of AI will continue to grow and revolutionize the clinical trial process. Powerful AI tools will complement the efforts of research partners and play a transformative role in improving their ability to develop beneficial and life-saving treatments.

ORGANIZATION

Navis Bio

CONTACT

Nives Rombini 

Jonas Walheim 

ORGANIZATION TYPE

Industry

IMPLEMENTATION DATE

2024

TOPIC

Quality

RELATED CTTI PROJECT

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

CTTI RESOURCES

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