SIAPARTNERS

Challenges and Best Practices when Implementing a GenAI tool for Clinical Trials Operations

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Abstract

Artificial Intelligence (AI) has been a key component of drug, biopharma, and biotechnology development for many years (Bhinder, Glivary, Madhukar, & Elemento, 2021) (NGalleo, Naveriro, Roca, Rios Insua, & Capillo, 2021) (Artico, Arthur, & Langham, 2022) (Mayorga-Ruiz, 2019). More recently, there has been an increased interest in using generative AI (GenAI) in the development/clinical trial space (Maniar, 2024). The ability to utilize natural language queries and automate the real-time generation of documents and data insights has the potential to significantly reduce cost and time, mitigate risks, and improve the interactions between the study sponsor and the study participants.

However, few examples and guidance exist on implementing a generative AI system for clinical trial use. This paper provides a discussion of what should be considered when implementing GenAI, an implementation checklist, and a step-by-step example of implementing a generative AI system and solution. This example is the implementation of SiaGPT, a generative AI solution developed by Sia Partners, to assist in documenting adverse events for a clinical trial based on publicly available papers regarding the compounds being used.

Introduction

There are many challenges with modern clinical trials regardless of therapeutic area or product type. First, the increasing cost of clinical trials continues to be one of the major challenges to bringing new products to the market. The estimated cost of developing and commercializing can be more than $4 Billion USD (Schlander, Hernandez-Villafuerte, Cheng, Mastre-Ferrandiz, & M, 2021) (Morgan, Grootendorst, Lexchin, Cunningham, & Greyson, 2011) (Moore, 2018) (DiMasi, Grabowski, & Hansen, 2016). Second, there is an increased recognition of the need for greater diversity of study data (Getz & Campo, 2019). This diversity is not only related to characteristics such as geography, race, age, and gender but there is a growing recognition of the need to include trials that address socioeconomic differences (U.S. Food &Drug, 2020). Finally, the amount of data from clinical trials has become extensive and varied due to the incorporation of new technologies, such as omics and new data sources, e.g., Real-World-Evidence (RWE), which makes data analysis more difficult, adding to the complexity of modern clinical trials (Eichler & Sweeney, 2018).

Cost

The cost of clinical trials can vary widely depending on the trial type, trial phase, therapeutic area, and geographic region in which the trial is conducted. However, there are common elements that contribute to the overall cost of clinical trials. Many major drivers of clinical costs are difficult to reduce, such as clinical personnel costs, clinical site fees, registration fees, manufacturing the investigational product and testing. However, some cost contributors could be reduced using AI (generative or other). These costs include:

- General R&D Cost (Schlander, Hernandez-Villafuerte, Cheng, Mastre-Ferrandiz, & M, 2021): This includes the attrition and duration of clinical trials.
- Regulatory and Compliance Costs (Sertkaya, 2016) (Getz K. A., 2016) (Martin, 2017): This includes the expenses related to preparing regulatory submissions, as well as monitoring, overseeing, and maintaining compliance throughout the trial.
- Patient Recruitment and Retention Costs (Sertkaya, 2016): Finding and enrolling eligible patients for clinical trials can be a significant expense. Costs include site identification and selection, advertising and online recruitment campaign fees, and high overhead fees at many research institutions as well as retention strategies targeted to keep research sites and participants engaged throughout lengthy clinical trials over many years.
- Data Management and Analysis Costs (Sertkaya, 2016) (Eisenstein, 2005): Collecting, managing, and analyzing data generated during the trial requires a substantial budget, including electronic data capture (EDC) systems and other data technology for storing and capturing high volumes of information, including home and wearable devices.
- Monitoring and Quality Assurance Costs (Morrison, 2011) (Funning, 2009): Ensuring the trial follows Good Clinical Practice (GCP) guidelines involves, protocol development, documentation, monitoring, auditing, and quality assurance activities.

Data

The data in clinical trials is always enriched when new technologies for data capture are available. In today's clinical trials, this means not only the ability to capture new types of data (e.g., genomics, newly discovered biomarkers, new medical imaging modalities), but also, by utilizing advances in communication (Rosa, 2015) (Occa, 2024) and sensory technology (Walton, 2020) (Coravos, 2020), traditional data can be captured in a variety of new ways, such as the utilization of wearable devices (Izmailova, 2018) (Izmailova E. M., 2019)and the capture of RWE from commercial electronic data systems (i.e., EMRs) (Lamberti MJ, 2018). The constantly growing data ecosystem means there is an increased need for tools that can (a) manage the tasks of data aggregation and federation, (b) that can help with data visualization and analysis, (c) that can assist in the assurance of data quality, (d) that can assist in regulatory compliance in capture and use, and, as more data are shared, (e) that can assist in data anonymization. Some of the key contributors to the complexity of modern clinical trial data are:

- Genomic and Biomarker Data: With the advent of precision medicine, many clinical trials now include genomic and novel biomarker data. This data provides valuable insights into individual patient characteristics, allowing for more targeted and personalized treatment approaches. It also can add significant amounts of data (Ginsburg, 2021). The average size of a single NGS run is around (1-3 GB) (ThermoFisher), and there may be hundreds of thousands of NGS runs in any given trial. NGS runs are just one of potentially thousands of data elements.
- Real-World Data Integration: Modern clinical trials often incorporate RWE, from various sources, such as electronic health records, insurance claims databases, patient registries, and social media. RWE helps researchers better understand the long-term effectiveness and safety of interventions, and can help eliminate data bias (Jie, Zhiying, & Li, 2021) (Lamberti MJ, 2018) (Cracchiolo, 2023).
- Advanced Imaging: Advanced medical imaging generates high-resolution data, which can be used in clinical trials to assess treatment responses or disease progression in more detail (Ashton, 2013) (Huang, 2017). In addition, optical techniques are also being explored to replace many of the chemical-based diagnostic tools. However, as with many omics technologies, imaging data requires a significant amount of storage and processing power. For example, the average ultrasound image is about 5 MB. MRI and CT data could be more than ten times that amount.
- Electronic Patient-Reported Outcomes (ePROs): Many trials now collect patient-reported outcomes electronically, providing a wealth of data on patient experiences, symptoms, and quality of life during the trial. However, these tools can be challenging for the patient to use because of lack of standardization in data capture, especially for less technology-savvy participants (Li, 2023) (Seppen, 2023) (Cracchiolo, 2023).
- Omics Data: In addition to genomics, many other "omics" technologies are becoming routine in clinical trials, such as proteomics and metabolomics. As with genomics, these generate extensive data related to the molecular underpinnings of diseases and treatment responses and often require significant data storage and processing (McShane, 2013) (Zielinski, 2021) (Hernandez-Martinez, 2019).
- Real-Time Data Monitoring: Real-time and remote patient monitoring through digital health tools generate continuous data streams during clinical trials, enabling adaptive trial design and quicker identification and response to safety or efficacy signals (Wang, 2022).
- Patient-Centric Trials: Patient-centric trials, which focus on patient preferences and outcomes, require the collection and analysis of a broader range of patient-generated data and account for alternative trial designs to achieve the goal of reducing the burden to participate in clinical trials. This is a growing trend where the patient can essentially "shop" their health data or choose a variety of options to improve availability to participate in a clinical trial and retention rates once enrolled.
- Regulatory Requirements: Regulatory agencies are requiring more extensive data collection and reporting to support the approval of new treatments, especially in cases of rare diseases or advanced therapies. Therefore, there is a constant need to ensure that the data captured, and its analysis are formatted and compliant with regulations that may evolve during clinical development or even during a clinical trial (Shuren, 2023) (Levine, Oyseter, & Purcell, 2023).

Patient Recruitment and Selection

Recruiting patients for clinical trials can be a complex and challenging process (Pasha AS, 2023). The need for study participant diversity, the desire for trial decentralization, and efforts to extend trials globally make these challenges even more complex. Some of the challenges with clinical trial recruitment include (Aissel, 2024) (Laaksonen, et al., 2022):

- Strict Inclusion and Exclusion Criteria: Clinical trials often have stringent eligibility criteria, which may exclude many potential participants. These criteria are designed to ensure the safety of participants and the validity of trial results, but they can limit recruitment.
- Lack of Study Awareness (Joshi, 2012) (Massett, 2017): Some individuals, especially those from disadvantaged backgrounds, may have limited access to information and healthcare resources, making it challenging to learn about and/or participate in a clinical trial.
- Geographic Barriers (Soares, 2021) (Seidler, 2014) (Soares R. R., 2023): Clinical trials may be conducted at specific research centers, making participation difficult for individuals who live in remote or underserved areas. Decentralized clinic trial approaches hope to address some of these challenges but can create issues more with language barriers and technology readiness differences.
- Language and Cultural Barriers (Kurt, 2017) (Smith, 2018): As trials expand globally, language and cultural differences can pose challenges in recruitment, as it may be difficult to effectively communicate the purpose and requirements of the trial to individuals from diverse backgrounds.
- Logistical Hurdles (Mahon, 2016): The logistics of participating in a clinical trial, such as appointment scheduling, transportation, employment obligations and childcare, can present significant challenges for potential participants.
- Adverse Events and Side Effects Concerns: The potential for adverse events or side effects can deter individuals from participating in clinical trials. Concerns about experiencing negative health outcomes can be a barrier.
- Inconvenient Study Protocols: Lengthy or complicated study protocols, including frequent clinic visits, numerous tests, or dietary restrictions, can discourage potential participants.

Background on GenAI

GenAI is a type of artificial intelligence trained on large datasets of existing content. It then uses that knowledge to generate new content similar to the training data.

Several technologies, including deep learning and natural language processing, are used for generative AI. Deep learning is a type of machine learning that uses artificial neural networks to learn complex patterns from data without being explicitly programmed. It does this by algorithm training and creates a resulting model. Because of this, quality data is required as part of the training set so as not to introduce false or invalid data. This is also where bias can be introduced. For example if the training data only contains information about a patient population of 35–45-year-olds, the resulting model may be ineffective or wrong for children or the elderly. Once trained, removing data from the resulting models is difficult, if not impossible.

Natural language processing is a field of computer science that deals with the interaction between computers and human language. It allows for using natural language, instead of a programming language or other specialized languages designed for computer interactions, to query data. It also allows for memory so follow-up questions can be asked based on the previous questions and answers.

Some typical use cases for GenAI are:

- Chatbots: allow clinicians to ask questions about the protocol or data; enable patients to explain their symptoms and get advice on what to do about them.
- Translating languages: Existing content on a web form can be translated into the user’s language in real time.
- Speech-to-Text: creating transcripts of medical encounters with proper spelling and terminology.
- Automating tasks: data from a transcript can be processed into an EMR with standard formatting and coding.

How can GenAI address clinical trial challenges?

GenAI has the potential to significantly address many of the challenges in modern drug development and with clinical trials specifically. Several groups are exploring different uses of generative AI in areas such as facilitating digital twins (Bordukova, 2023), optimizing clinical trial design (Aliper, 2023), and even mimicking clinical trial data (Eckardt, 2024). In general terms, GenAI can automate many communication and documentation activities. For example, AI can assist in generating compliant documents for activities, such as study designs, consent forms, investigator brochures and study result summaries. GenAI could also capture patient-reported outcomes and adverse events regardless of differences in language, technology readiness, or economic status. With the assistance of AI, there can be an assurance that the data are captured in an interoperable and compliant manner, thus protecting the quality and usability of the data.

Another area where GenAI could play a major role is in study participant recruitment and maintenance. Oftentimes, the recruitment of study participants is slow and laborious due to the inclusion and exclusion criteria of the trial. Traditional recruitment strategies involve outreach to specific clinical sites or investigators and/or advertising in mass media such as social media, online, and via television or news sites. More recently, automated scans of electronic health records (EHRs) have helped speed up the identification of eligible participants. For example, IBM Watson has a tool specific for meta-analysis of Electronic Health Records systems (Jie, Zhiying, & Li, 2021). However, this is limited by the amount of data that is either only available as unstructured or semi-structured data in EHRs in clinical notes, often using the complexity of abbreviations, misspellings, jargon, typographical errors, and important information in other formats like radiology reports. Generative AI can potentially overcome these limitations by combining the natural language processing of GenAI with recognized ontologies such as SNOMED. Using this approach, it is possible to harmonize clinical information from various sources. (National Library of Medicine, 2016). Furthermore, generative AI can search for potential subjects in non-traditional clinical platforms, such as social media. Once identified, AI can further streamline processes and verify that a subject meets inclusion and exclusion criteria, answer any of the potential subject's questions in real time, and assist in the consenting and onboarding processes without needing the subject to travel. Once enrolled, AI can then assist subjects in reporting outcomes and adverse events in such a way as to maintain the data quality and usability.

A third area where AI can assist clinical trials is with regulatory compliance. Regulations for developing healthcare products (e.g., FDA regulations or EU regulations) are constantly evolving. Given the length of time (i.e., years) for the development of a healthcare product, it is likely that during product development, a regulatory change will impact how a product is developed, how safety and efficacy are demonstrated, how trials are conducted, what data are needed for approval, or even what the responsibilities are for a product developer post commercialization. AI tools can be trained to first monitor for changes in relevant regulations and then alert the product developer with easy-to-consume summaries. If a change is determined to be significant, AI can then help with any revisions that may be needed to form documents, or protocols.

Finally, AI can help reduce the burdens of clinical trial data management and analysis. For example, GenAI can help implement natural language-based data capture from study investigators and participants allowing for the use of jargon and eliminating the need to user interpretation. This should improve data quality and completeness as well as decrease the burden of data entry. In addition, AI can generate on-demand data summaries from complex data sets. These summaries can be incorporated into a data dashboard, thus giving users a real-time view of trial data with on-demand reporting.

Challenges in implementing AI

Data Quality

As with all AI-driven systems, GenAI heavily relies on high-quality data. Limited, incomplete or biased data can lead to misinformation or even inaccurate results. Therefore, ensuring a statistically representative high-quality and diverse dataset for an AI implementation is critical. This can be particularly challenging when incorporating data that contains RWE. As that data is aggregated, there will need to be an accurate mapping of key terms so that the data's meaning and relevance are not lost. This mapping can be particularly difficult when datasets from diverse populations or multiple types of organizations are merged. Therefore, it is important that in the aggregation process and when developing data visualization tools, the data scientist involved understands how the data will be used.

Regulatory Approval

Incorporating GenAI into clinical trials will require acceptance by regulatory bodies, such as the US FDA, EMA, and/or MHRA. Especially if tools such as GenAI are responsible for capturing and reporting clinical outcomes or adverse events. Regulators have recognized the need to adapt their regulation as new AI/Machine Learning technologies penetrate healthcare. To that end, the FDA recently published several guidelines for developers of AI/Machine Learning based medical software "Proposed regulatory Framework for Modifications of Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)" FDA (2021), and "Clinical Decision Support Software, Guidance for Industry and Food and Drug Administration Staff" FDA (2022). Similar approaches, as outlined in these guidelines, will likely be used to assure regulators of the validity of the utilized GenAI-based tools in clinical trials. Therefore, it will be important that as tools are developed, the impact on regulatory compliance and product registration should be considered and the regulatory landscape should evolve as well.

Privacy and Security

Integrating GenAI in clinical trials raises important ethical and data safety considerations. The use of GenAI for analysis of RWE, the capture of adverse events, and many other potential applications will involve personal health information and potentially identifiable information. Therefore, the developers of AI tools will need to consider current privacy and security regulations and guidelines during development and will need to monitor for changes in regulations that may require modifications of the tool(s). In addition, there should be a robust and ongoing security testing plan for the tools. This plan should ensure that updates to the tools don't introduce new issues as well as that ongoing testing is performed to guard against new threats to the system. This will not only protect the data security but could also help ease privacy concerns of potential trial participants.

Implementation Best Practices

Implementing GenAI systems in clinical research requires a structured approach encompassing model development, ethical considerations, deployment, monitoring, and continuous improvement (Reddy, 2021) (Jin, 2019). This requires involvement from a multidisciplinary team with expertise in data science, software engineering, ethics, regulatory and clinical trial domain-specific knowledge to ensure the success of the GenAI project.

Implementing GenAI systems, whether for natural language processing, image generation, or other applications, involves several critical steps to ensure successful and responsible deployment, many of which are standard practices for implementing any AI system. A specific difference, however, is that when using GenAI models, most users will be fine-tuning an existing GenAI large language model (LLM) and not creating their own. The reason is that the GenAI LLMs are massive and take tremendous resources to build, so only a few companies can invest in developing novel LLMs, such as OpenAI, Anthropic, Meta, Google, Microsoft, and IBM. Implementation for a typical AI application requires an empty dataset and, thus, complete control of what the model is trained on. For a GenAI application, selecting the best foundation model is essential, as it cannot be changed once selected. The model can only be enhanced by adding domain-specific data to help it produce improved results for a specific use case.

Implementation Checklist for a GenAI System

When preparing to use GenAI to solve any problem, a set of requirements for that system should be devised. This will help guide the implementation and deployment of a system that performs as desired, is secure, and is easy to use. What follows is a checklist and how it was used to create a representative use case, which will be discussed in detail in the subsequent section. The representative use case and representative system for this and the next section will focus on the use of generative AI by someone compiling an Investigational New Drug (IND) application and using the generative AI tool SiaGPT developed by Sia Partners (SiaGPT). SiaGPT is an ideal tool for such an application because the user can upload their own documents in a secure environment where the LLM feature can be used to compare, investigate, analyze, and summarize the uploaded documents. Many items in this checklist may not apply to all use cases, and there may be specific requirements or tasks that need to be added for others. This is meant as a representative list.

Figure 1 Estimated potential CO2e emissions savings with eB/L per year 2

Task/Requirements	SiaGPT (Sia Partners, n.d.) Use Case
1. Define the Problem and Use Case: Clearly define the problem aimed to solve using GenAI and the specific use case for its application.	A researcher studying a new injectable drug is compiling information for an Investigation New Drug (IND) application to the FDA. As part of the application, the researcher prepares the information for clinical investigators and would like to include information in the investigator documentation that describes the adverse events that may be encountered from the adjuvant that will be used in the drug formulation; in this case, the adjuvant is ALFQ. The information required for the documentation can be found in numerous published articles, which the researcher has access to but knows it will take numerous hours to review all the articles to find the adverse event information needed for the document. The researcher would like to use a generative AI solution (in this case, SiaGPT)
2. Data Collection and Preparation: Collect and curate high-quality data relevant to the problem. Clean and preprocess the data, handling missing values and outliers.	Downloaded user manuals and data sheets from blood pressure cuff manufacturers (PDF, websites, word files in any language); previous study protocols and site manuals (which contain device user manuals), contracts, or other listed device pricing from device distributors, user kit instructional guides (Spanish and English)
3. Select the Model Architecture: Choose the appropriate AI/ML model (e.g., GPT-3/4, GAN, LSTM) based on the problem's requirements.	The generative AI technology GPT-4 was selected based on the problem statement and the need to generate related documents.
4. Data Splitting: Split the data into training, validation, and test sets to evaluate the model's performance.	The system will be trained on a subset of the instructional guides and study protocols. The remaining will be used for validation.

Task/Requirements	SiaGPT (Sia Partners, n.d.) Use Case
5. Model Training: Train the AI model using the training data while monitoring training metrics. Tune hyperparameters, such as learning rates, batch sizes, and network architecture, for optimal performance.	SiaGPT has training metrics that are reviewed, and human annotators can improve parameter detection by adding additional data or removing non-applicable documents.
6. Regularization and Optimization: Apply regularization techniques (e.g., dropout, batch normalization) to prevent overfitting. Optimize the model's performance through techniques like gradient clipping or weight decay.	This task is not needed for this example. However, it can be a critical activity for non-GPT applications.
7. Evaluation Metrics: Define appropriate evaluation metrics (e.g., accuracy, F1 score, perplexity) for your AI model.	For this example, a manual review of the resulting data table and instructional manual for accuracy and readability
8. Model Validation: Validate the model's performance using the validation dataset and fine-tune as necessary.	The instructional guides generated by the SiaGPT will be compared to previous guides for validation (accuracy of content, format, translation, etc...)
9. Ethical and Responsible AI Considerations: Ensure that the GenAI model complies with ethical guidelines and does not generate harmful or biased content.	This task is not needed for this example. However, it can be critical for other applications, especially if the activity involves patient-level demographics.
10. Data Privacy and Security: Implement safeguards to protect sensitive or private data used during training or generation.	For this example, only public information containing non-confidential data was used. However, if any externally facing usage or confidential data, such as patient-level data, were used, then security at the data access level would be needed.
12. Scalability and Performance: Optimize the AI model for production use, ensuring scalability, low latency, and high availability.	Since this uses a commercial application, SiaGPT, already in production, scalability was not considered.
13. User Interface or Integration: Design a user interface or integrate the AI system into existing applications or workflows.	In this example, the commercial tool used, SiaGPT, already has a natural language chatbot interface.

Task/Requirements	SiaGPT (Sia Partners, n.d.) Use Case
14. Testing and Quality Assurance: Conduct thorough testing, including unit testing, integration testing, and user testing. Ensure that the model behaves as expected and handles edge cases.	The application was evaluated by multiple users familiar with clinical trial protocols to verify the system outputs.
15. Monitoring and Logging: Set up continuous monitoring of the GenAI system for performance, security, and data drift. Implement detailed logging to trace model inputs, outputs, and errors.	Although this is not a requirement for this example, the SiaGPT system has a user-specific logging function that captures time and date-stamped information for each session. If necessary, this information can be used to create an audit trail.
16. Compliance and Regulations: Ensure compliance with relevant data protection and AI-related regulations, such as GDPR or HIPAA.	For this example, no patient-level data were used, and security and privacy compliance (GDPR and HIPAA) were not applicable.
17. User Training and Education: Provide training and guidelines to users who will interact with the AI system.	The advantage of a GPT application, such as SiaGPT, is that it is designed to be intuitive and requires minimal or no training.
18. Feedback Loop: Implement a feedback mechanism to gather user feedback and improve the model over time.	If this example were implemented for routine use, it would be expected to allow users to add and update the device data.
19. Security: Protect the AI system against potential attacks, such as adversarial attacks or data poisoning.	In this example, the application is hosted by the manufacturer, Sia Partners, who provides security. The SiaGPT system is ISO 27001 compliant.
20. Documentation: Maintain comprehensive documentation for the AI system, including model architecture, deployment procedures, and user guides.	For this example, a workflow document and video were created to train users to use the system.
21. Disaster Recovery and Redundancy: Establish disaster recovery plans and redundant systems to ensure system stability in case of failures.	For this example, since the commercial supplier hosted the application, additional disaster recovery planning and redundancy were not needed. If one was to internally host the application, then these requirements would need to be met.
22. Legal Agreements: Establish any necessary legal agreements for intellectual property, data usage, or service-level agreements.	This does not apply to this example. In general, however, a party using SiaGPT will need to sign a Terms of Service (TOS) agreement

Task/Requirements	SiaGPT (Sia Partners, n.d.) Use Case
23. Performance Metrics: Continuously monitor performance metrics and gather user feedback to improve the AI system.	This does not apply to this example. Generally, it is good practice to at least have a feedback method to gain user experiences and struggles.
24. Regulatory Compliance: Ensure ongoing compliance with changing regulations and adapt the system as necessary.	See answer to 16
25. Ethical and Responsible AI Audits: Regularly audit the GenAI system to detect and mitigate ethical and bias issues.	For this example, this task is not needed. However, for other applications, this can be a critical activity, especially if the activity involves patient-level demographics.
26. Updates and Maintenance: Plan for regular model updates, maintenance, and patches to address vulnerabilities or improve performance.	The commercial supplier hosted the application and is responsible for maintenance and updates, as indicated in the terms of service.
27. Security Incidents and Response: Develop a security incident response plan to address any security breaches or issues promptly. Demonstration of the use of GenAI in support of a clinical study design.	This does not apply to this example.

Implementation Process: an example of the use of GenAI to support clinical trials.

The following example will use SiaGPT to demonstrate the process of identifying adverse events that may be seen in a clinical study using the adjuvant ALFQ based on published safety data. As this is just an example, we will focus on the AI and database portions of the project. We will not implement any automation for searching the Internet for safety data and will have those documents pre-loaded into the SiaGPT system.

Adding Data

The first step in getting SiaGPT ready is to obtain published data that could be useful in our search. In this case, that's a set of peer-reviewed papers related to ALFQ in various other trials and safety studies. We obtained PDFs of these papers, created a new project, and added these documents to the new project. This is a straightforward process that was completed in a web browser. The SiaGPT system then processes these files which takes only a few minutes.

Updating Data

If additional papers are found or an automated system to search for them on the Internet is created, they can be uploaded and will become available as part of the database for future searches.

Another feature of SiaGPT is that you can remove documents from the system. In a traditional LLM, removing data is very difficult. But with SiaGPT, it's as easy as selecting one or more documents and telling the system to delete them. In this case, one could do that if a paper was retracted or if a document is not relevant to the goal.

Deploying Updated Systems

In a production system, one would want to test the newly updated data before deploying it for general use. This could be done with a processing pipeline that would take the updated documents and ingest them, run some queries against the new dataset to ensure we get back the expected results, and then deploy the validated system for use. This is a standard CI/CD (continuous integration/continuous deployment) pipeline that ensures a timely deployment of updated systems and the quality of those systems. If the results of the test queries are unacceptable, notice could be sent to the administrator of the system to identify the problem. This would ensure the system is not deployed for general use until the quality is acceptable. This also protests from updates that make the system worse in some way.

Effort to Build and Maintain

For this example, 11 papers in PDF format were uploaded. The manuals ranged in size from 570KB to 3.6MB. The total upload time was less than a minute, and the documents were all processed within ten minutes. The entire process is automated once the upload starts. The only human activity was collecting the files and placing them in a directory on a PC. The SiaGPT site allows uploading an entire directory, so that's what was done.

Maintaining the system could be automated. The automation process would follow a real device selector guide:

- Identify papers relevant to the safety of ALFQ.
- Create a web scraping tool that could search for new papers (those we don't already have in our system) related to the safety of ALFQ.
- Upload new papers to the documents store in our project.

Example Usage

Once the documents are uploaded and processed, one can interact with them via the SiaGPT chatbot interface to get the information desired. The following is an example of summarizing safety information for a clinical trial using the Summarizer agent that is part of the default SiaGPT configuration and where the representative user is "Latham".

Latham 4/16/2024, 9:54:48 AM

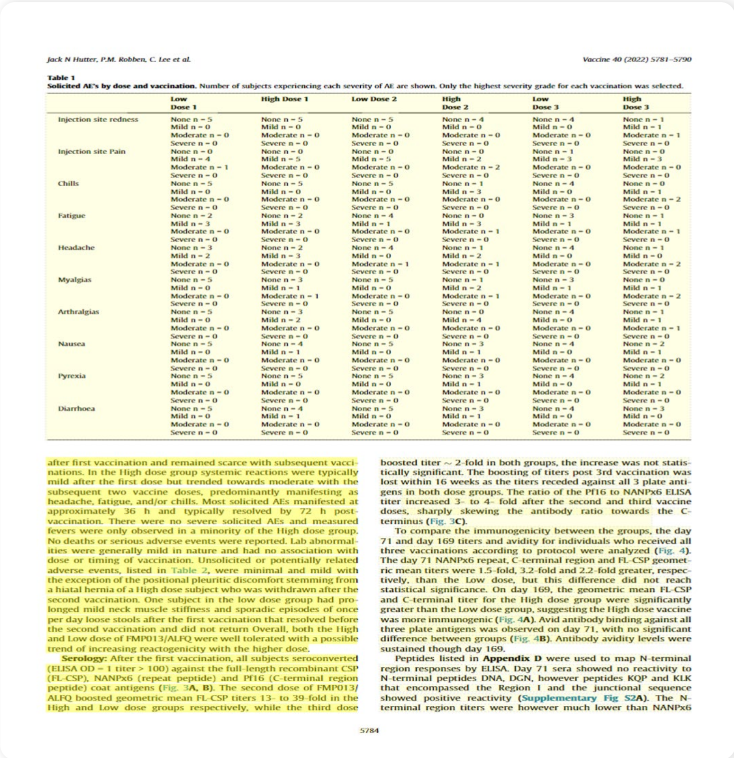
What specific adverse events were reported in the studies involving the administration of ALFQ in healthy adults?

Summarizer 4/16/2024, 9:54:48 AM

The adverse events reported in studies involving the administration of ALFQ in healthy adults included headache, fatigue, chills, lab abnormalities, mild neck muscle stiffness, and sporadic episodes of once per day loose stools.

Sources: papers_Hutter_2022_ALFQ_Clincal_Trial_-_Malaria.pdf... p.4 ¶3

At this point, there is a summary of the adverse events found and a reference to a specific document where this information was found. Additional information and context can be obtained by clicking on that source paper and a reading pane will show the original document at the page where this information was found:



Jack N Hutter, P.M. Robben, C. Lee et al. *Vaccine 40 (2022) 5781–5790*

Table 1
Solicited AE's by dose and vaccination. Number of subjects experiencing each severity of AE are shown. Only the highest severity grade for each vaccination was selected.

	Low Dose 1	High Dose 1	Low Dose 2	High Dose 2	Low Dose 3	High Dose 3
Injection site redness	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 4 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 4 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 1 Mild n = 1 Moderate n = 1 Severe n = 0
Injection site Pain	None n = 0 Mild n = 4 Moderate n = 1 Severe n = 0	None n = 0 Mild n = 5 Moderate n = 0 Severe n = 0	None n = 0 Mild n = 5 Moderate n = 0 Severe n = 0	None n = 0 Mild n = 2 Moderate n = 2 Severe n = 0	None n = 1 Mild n = 3 Moderate n = 0 Severe n = 0	None n = 0 Mild n = 3 Moderate n = 0 Severe n = 0
Chills	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 1 Mild n = 3 Moderate n = 0 Severe n = 0	None n = 4 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 0 Mild n = 1 Moderate n = 2 Severe n = 0
Fatigue	None n = 2 Mild n = 3 Moderate n = 0 Severe n = 0	None n = 2 Mild n = 3 Moderate n = 0 Severe n = 0	None n = 4 Mild n = 1 Moderate n = 0 Severe n = 0	None n = 0 Mild n = 3 Moderate n = 1 Severe n = 0	None n = 3 Mild n = 1 Moderate n = 0 Severe n = 0	None n = 1 Mild n = 1 Moderate n = 1 Severe n = 0
Headache	None n = 3 Mild n = 2 Moderate n = 0 Severe n = 0	None n = 2 Mild n = 3 Moderate n = 0 Severe n = 0	None n = 4 Mild n = 0 Moderate n = 1 Severe n = 0	None n = 1 Mild n = 2 Moderate n = 1 Severe n = 0	None n = 4 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 1 Mild n = 0 Moderate n = 2 Severe n = 0
Myalgias	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 3 Mild n = 1 Moderate n = 1 Severe n = 0	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 1 Mild n = 2 Moderate n = 1 Severe n = 0	None n = 3 Mild n = 1 Moderate n = 0 Severe n = 0	None n = 0 Mild n = 1 Moderate n = 2 Severe n = 0
Arthralgias	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 3 Mild n = 2 Moderate n = 0 Severe n = 0	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 0 Mild n = 4 Moderate n = 0 Severe n = 0	None n = 4 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 1 Mild n = 1 Moderate n = 1 Severe n = 0
Nausea	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 4 Mild n = 1 Moderate n = 0 Severe n = 0	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 3 Mild n = 1 Moderate n = 0 Severe n = 0	None n = 4 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 2 Mild n = 1 Moderate n = 0 Severe n = 0
Pyrexia	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 3 Mild n = 1 Moderate n = 0 Severe n = 0	None n = 4 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 2 Mild n = 1 Moderate n = 0 Severe n = 0
Diarrhoea	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 4 Mild n = 1 Moderate n = 0 Severe n = 0	None n = 5 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 3 Mild n = 1 Moderate n = 0 Severe n = 0	None n = 4 Mild n = 0 Moderate n = 0 Severe n = 0	None n = 3 Mild n = 0 Moderate n = 0 Severe n = 0

after first vaccination and remained scarce with subsequent vaccinations. In the High dose group systemic reactions were typically mild after the first dose but trended towards moderate with the subsequent two vaccine doses, predominantly manifesting as headache, fatigue, and/or chills. Most solicited AEs manifested at approximately 36 h and typically resolved by 72 h post-vaccination. There were no severe solicited AEs and measured fevers were only observed in a minority of the High dose group. No deaths or serious adverse events were reported. Lab abnormalities were generally mild in nature and had no association with dose or timing of vaccination. Unsolicited or potentially related adverse events, listed in Table 2, were minimal and mild with the exception of the positional pleuritic discomfort stemming from a hiatal hernia of a High dose subject who was withdrawn after the second vaccination. One subject in the low dose group had prolonged mild neck muscle stiffness and sporadic episodes of once per day loose stools after the first vaccination that resolved before the second vaccination and did not return Overall, both the High and Low dose of FMP013/ALFQ were well tolerated with a possible trend of increasing reactogenicity with the higher dose.

Serology: After the first vaccination, all subjects seroconverted (ELISA OD = 1 titer > 100) against the full-length recombinant CSP (FL-CSP), NANPx6 (repeat peptide) and Pf16 (C-terminal region peptide) coat antigens (Fig. 3**A, B**). The second dose of FMP013/ALFQ boosted geometric mean FL-CSP titers 13- to 39-fold in the High and Low dose groups respectively, while the third dose boosted titer ~ 2-fold in both groups, the increase was not statistically significant. The boosting of titers post 3rd vaccination was lost within 16 weeks as the titers receded against all 3 plate antigens in both dose groups. The ratio of the Pf16 to NANPx6 ELISA titer increased 3- to 4- fold after the second and third vaccine doses, sharply skewing the antibody ratio towards the C-terminus (Fig. 3**C**).

To compare the immunogenicity between the groups, the day 71 and day 169 titers and avidity for individuals who received all three vaccinations according to protocol were analyzed (Fig. 4). The day 71 NANPx6 repeat, C-terminal region and FL-CSP geometric mean titers were 1.5-fold, 3.2-fold and 2.2-fold greater, respectively, than the Low dose, but this difference did not reach statistical significance. On day 169, the geometric mean FL-CSP and C-terminal titer for the High dose group were significantly greater than the Low dose group, suggesting the High dose vaccine was more immunogenic (Fig. 4**A**). Avid antibody binding against all three plate antigens was observed on day 71, with no significant difference between groups (Fig. 4**B**). Antibody avidity levels were sustained though day 169.

Peptides listed in **Appendix D** were used to map N-terminal region responses by ELISA. Day 71 sera showed no reactivity to N-terminal peptides DNA, DGN, however peptides KQP and KLK that encompassed the Region I and the junctional sequence showed positive reactivity (**Supplementary Fig S2A**). The N-terminal region titers were however much lower than NANPx6

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In addition, SiaGPT suggests some follow-up questions that may be relevant based on the data in the papers that it scanned:

What were the main findings or conclusions regarding the immune response to antigen adsorbed to aluminum hydroxide particles in the studies involving ALFQ adjuvant in healthy adults?

What markers of tissue damage were observed in Rhesus following ALFQ administration, and how do they compare to those reported following AS01 administration?

What were the most common solicited adverse events reported after the administration of ALFQ in healthy adults, and how did they vary between the high and low dose groups?

What were the observed transient local reactions in Rhesus macaques receiving 1 mL of ALFQ during the vaccination study?

Clicking on any of these questions will continue the chat with that question. However, what if one wants more detailed information about the initial question? In addition to the Summarizer, an Advanced agent can do much more than summarize documents. For example, the same question asked of the Advanced agent produced the following:

Latham 4/16/2024, 10:26:10 AM

What specific adverse events were reported in the studies involving the administration of ALFQ in healthy adults?

Advanced 4/16/2024, 10:26:11 AM

I have gathered the following information from the provided documents:
➸ Specific adverse events reported in the study involving the administration of ALFQ in healthy adults included headache, fatigue, chills, lab abnormalities, positional pleuritic discomfort, mild neck muscle stiffness, and sporadic episodes of loose stools. These adverse events were monitored through 7 days post-vaccination, along with unsolicited adverse events and serious adverse events (SAEs) through the final study visit. The clinical safety profile was deemed acceptable for FMP013 with no serious adverse events reported. papers_Hutter_2022_ALFQ_Clincal_Trial_-_Malaria.pdf... p.2 ¶3, papers_Hutter_2022_ALFQ_Clincal_Trial_-_Malaria.pdf... p.4 ¶3, papers_Hutter_2022_ALFQ_Clincal_Trial_-_Malaria.pdf... p.1 ¶4

Conclusion: The specific adverse events reported in the study involving the administration of ALFQ in healthy adults were headache, fatigue, chills, lab abnormalities, positional pleuritic discomfort, mild neck muscle stiffness, and sporadic episodes of loose stools, with no serious adverse events reported.

As shown above more detailed information and more references are obtained with the Advanced agent. There is a summary in the conclusion section, as well. Another representative use of the Advanced agent is determining the reactions may have been caused by the use of ALFQ:

Latham 4/16/2024, 10:30:43 AM

What were the most common systemic reactions reported in the High dose group after the first dose of ALFQ vaccination?

Advanced 4/16/2024, 10:30:43 AM

I have gathered the following information from the provided documents:

➳ The most common systemic reactions in the high dose group after the first dose of ALFQ vaccination were headache, fatigue, and/or chills. papers_Hutter_2022_ALFQ_Clincal_Trial_-_Malaria.pdf... p.4 ¶3

➳ Other reactions included pleuritic pain and night sweats. papers_Hutter_2022_ALFQ_Clincal_Trial_-_Malaria.pdf... p.5 ¶28

➳ Additional reactions reported were pyrexia, respiratory tract congestion, abnormal dreams, dizziness, and subjective fever. papers_Hutter_2022_ALFQ_Clincal_Trial_-_Malaria.pdf... p.5 ¶27

➳ Further reactions included myalgias, arthralgias, nausea, and pyrexia. papers_Hutter_2022_ALFQ_Clincal_Trial_-_Malaria.pdf... p.4 ¶5

Conclusion: The most common systemic reactions in the high dose group after the first dose of ALFQ vaccination included a range of symptoms such as headache, fatigue, chills, pleuritic pain, night sweats, pyrexia, respiratory tract congestion, abnormal dreams, dizziness, subjective fever, myalgias, arthralgias, and nausea.

In this example we can have the agent display the information in a table format.

Latham 4/16/2024, 10:34:22 AM

what is the frequency of local adverse events with ALFQ? Summarize results in a table by dose level. Show Adverse events as rows and dose levels as columns.

Advanced 4/16/2024, 10:34:22 AM

I have gathered the following information from the provided documents:

- The frequency of local adverse events associated with ALFQ is similar across different dose levels, with mild reactions experienced by a majority of volunteers after each vaccination.
papers_Hutter_2022_ALFQ_Clincal_Trial_-_Malaria.pdf... p.3 ¶3
- Local reactions at the vaccine site were scored on a 0-3 scale, with higher dose groups showing more common local reactions such as skin warmth, erythema, muscle swelling, and muscle induration compared to the 0.5 mL ALFQ dose group.
papers_Cawlfield_2019_ALFQ_Safety_Toxicity_and_Immunogenicity.pdf... p.4 ¶4

Conclusion:

Adverse Event	Low Dose (0.5 mL)	High Dose
Skin Warmth	Less Common	Common
Erythema	Less Common	Common
Muscle Swelling	Less Common	Common
Muscle Induration	Less Common	Common

This is just a sampling of the types of information one could glean from this dataset. Each response took less than a minute to come back, which is a massive time-saving process compared to reading each of these papers and then recalling the information necessary to answer these questions. However, as good general practice, given that generative AI is extracting information based on prompts by the user, one should always review the source information to confirm accuracy.

In summary, Generative AI, is and will continue to assist in streamlining pharmaceutical development with the goal of reducing time to market and overall costs. However, as with any tool, generative AI tools do have limitations that should be considered. Therefore, it is important that there is clear understanding of how and when to use generative AI in supporting clinical trials. In addition, efforts should be taken to select the right generative AI tool for the intended use and assuring the implementation of the tool is done with clearly articulated requirements as described here.

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