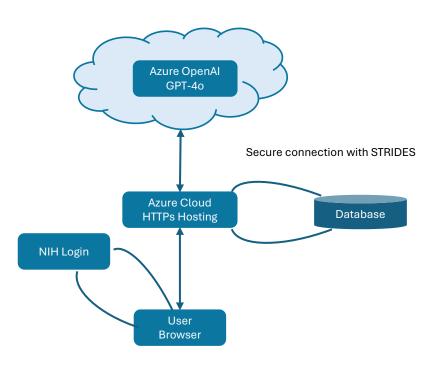


#### By clicking on Proceed you are agreeing to the above terms and conditions.

I Agree. Proceed

## **Process Narrative**

- User Prompt ->
- Combining with Context ->
- Sending the Request ->
- LLM Generates the Reply ->
- Reply Sent Back to the Web Server ->
- Saving the Conversation ->
- Displaying the Response



## Model or Interface

- Interface -
  - The view in your web browser that takes your message and shows the replies. It doesn't process or generate the response itself—it just sends your message to the model and displays the reply.

- Model-
  - The AI engine that actually generates the response. For NHLBI Chat, we use one of the pre-trained commercial "large language models" (llm) at Azure OpenAI such as GPT-3 or GPT-4.

## Model Details

- Training & cutoff dates
  - Models used in NHLBI Chat are commercial models, trained by OpenAI on general internet data (websites, forums, Wikipedia, etc.). Models are trained, tested and fine tuned for months or years. Once training is done, the model is frozen. They're not updated or retrained with new information. The "cutoff date" is the last date the training data was collected before training.
  - The model is not connected to the internet in real time. It can't perform searches or look up anything online. It relies entirely on what it already learned during its training period. Your interactions with NHLBI Chat are specific to you and not shared with other users. The model is never trained or fine tuned on your chats.

## **Random Nature of Responses**

- Like Autocomplete -
  - These are probability models that predict the next, most reasonable word for the context.
  - Because it's predicting based on probabilities, there's usually some variation in the responses.
  - You probably won't get the exact same reply every time, even if you enter the same prompt.
- Hallucinations
  - The data stored in an LLM is not fixed like in a database
  - These models may confidently and assertively generate accurate information.
  - It's always important to review the outputs carefully.

## **Prompting and Chat History**

- · What is Context -
  - The model knows nothing since the training cutoff date, so it's orientated to you via the prompt. You submit a message prompt, and the model replies – this is an exchange. To improve the model's understanding and context in the chat, when we send your prompt, we include some of your previous exchanges. The context we add is only from the exchanges of the current chat.
- What is Context LENGTH -
  - There is a context length limit, so working from the most recent exchange back, we only add exchanges up to that limit. That means the model can essentially "forget" what was discussed.
  - In NHLBI Chat, the current context lengths for the GPT-3.5 model is about 8,000 words. For the GPT-40 model the context length is approximately 24,000 words.

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Let's discuss how to present the clinical trial phases here at NHLBI to high school students in an infographic.

What I would like to do is to pull out the text from the clinical trial phases section, and organize it into a more friendly set of 4 side-by-side, vertical HTML panels with bright colors and appealing design – appropriate for a high school science classroom.

Here below is the text from the public website for general audiences. You may notice that the content-length for the different trial phases is not well balanced. in th final output, please try to keep the text balanced. There is a lot that can be derived from the larger text, and from your own knowledge to fill out gaps.

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What are clinical trials?

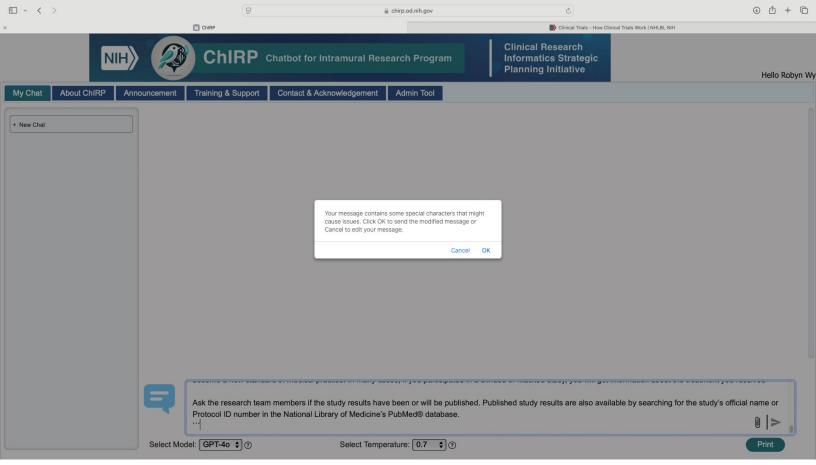
Clinical trials are medical studies that involve people like you. They help find new ways to prevent, detect, or treat diseases that are safe and effective. The National Heart, Lung, and Blood Institute (NHLBI) leads and supports many studies aimed at preventing, diagnosing, and treating heart, lung, blood, and sleep disorders.

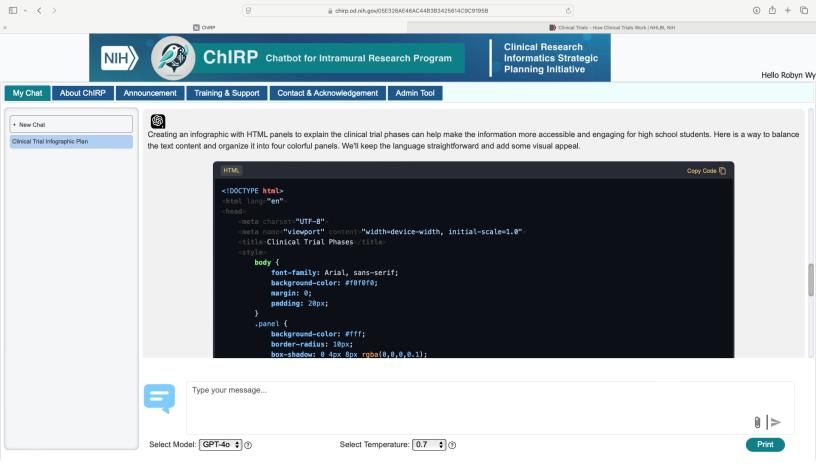
Clinical trials are an important part of the research spectrum. The idea for a clinical trial often starts in the lab. After researchers test new treatments or procedures in the lab and in animals, the most promising treatments are moved into clinical trials. As studies about new treatments move through a series of steps called phases, researchers learn more information about the treatment, its risks, and its effectiveness.

Each clinical trial has criteria describing who can join. Children as well as adults, patients and healthy volunteers, and people of a diverse range of ethnic and racial backgrounds can and are encouraged to participate in clinical trials.

Clinical trials follow a protocol, a carefully designed plan to safeguard your health and answer specific research questions. The protocol describes what you will be doing and what you can expect from the research team. It is important to understand the risks and benefits of participation before joining. You also have rights and protections as a participant in clinical trials.

National Institutes of Health (NIH) Institutes and Centers, including the NHLBI, support many types of clinical trials that contribute to medical knowledge and practice. Clinical trials can be described in a number of different ways, including by their purpose or by phase. Purpose of clinical trials





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N ChiRP		×	Clinical Trial Phases	

## Phase I: Safety First

Researchers test a new medicine or treatment in a small group of people for the first time. The goal is to find the best dosage and to learn about any side effects.

### Phase II: Effectiveness

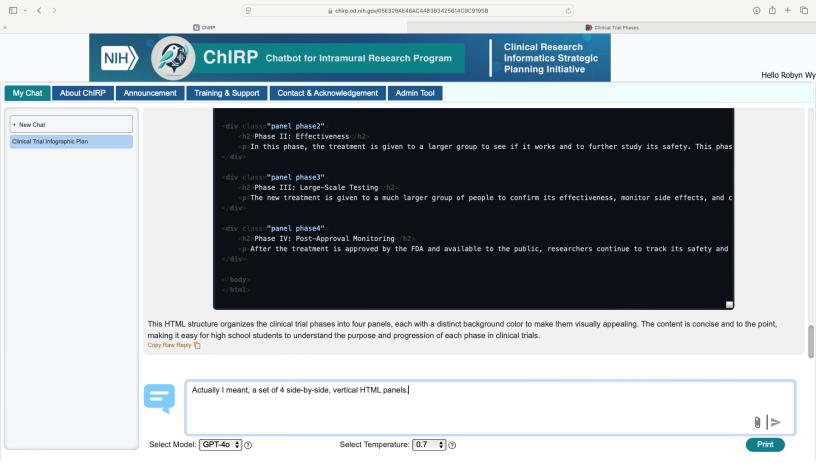
In this phase, the treatment is given to a larger group to see if it works and to further study its safety. This phase helps determine how effective the treatment is.

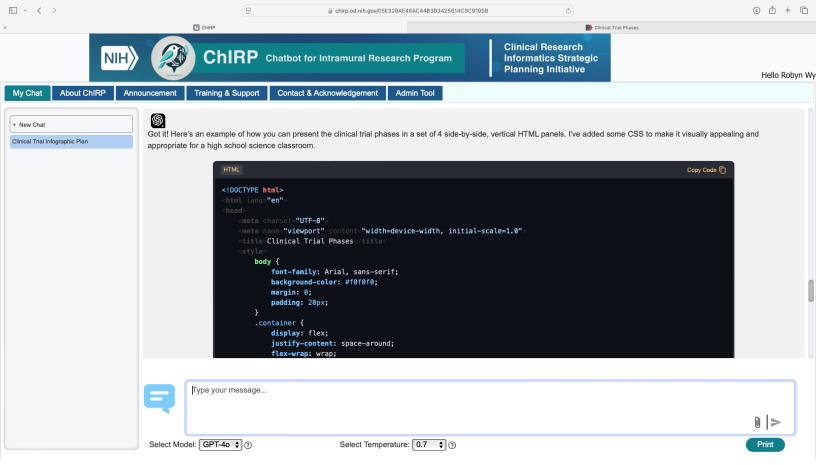
## Phase III: Large-Scale Testing

The new treatment is given to a much larger group of people to confirm its effectiveness, monitor side effects, and compare it with standard treatments or a placebo. This phase collects detailed information for safe use.

## **Phase IV: Post-Approval Monitoring**

After the treatment is approved by the FDA and available to the public, researchers continue to track its safety and gather more information on its benefits and optimal use in the general population.





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		×	Clinical Trial Phases	

## **Clinical Trial Phases**

Phase 1

Phase 1 trials test a new treatment in a small group of people for the first time. The goal is to learn about the treatment's safety and identify any side effects.

### Phase 2

Phase 2 trials focus on the effectiveness of the treatment. They involve more people than Phase 1 and gather preliminary data on whether the treatment works in people with a certain disease or condition.

## Phase 3

Phase 3 trials involve large groups of people to confirm the treatment's effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the treatment to be used safely.

### Phase 4

Phase 4 trials take place after the treatment has been approved for use by the FDA. These studies continue testing the treatment to collect information about its effects in various populations and any side effects associated with long-term use.



>> Search or enter website name

## **Clinical Trial Phases**

#### Phase 1

Phase 1 trials test a new treatment in a small group of people for the first time. The goal is to learn about the treatment's safety and identify any side effects.

## Phase 2

Phase 2 trials focus on the effectiveness of the treatment. They involve more people than Phase 1 and gather preliminary data on whether the treatment works in people with a certain disease or condition.

### Phase 3

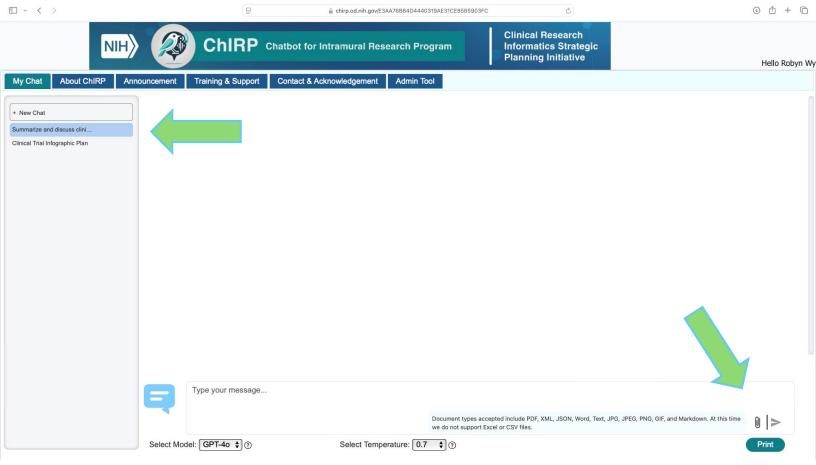
Phase 3 trials involve large groups of people to confirm the treatment's effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the treatment to be used safely.

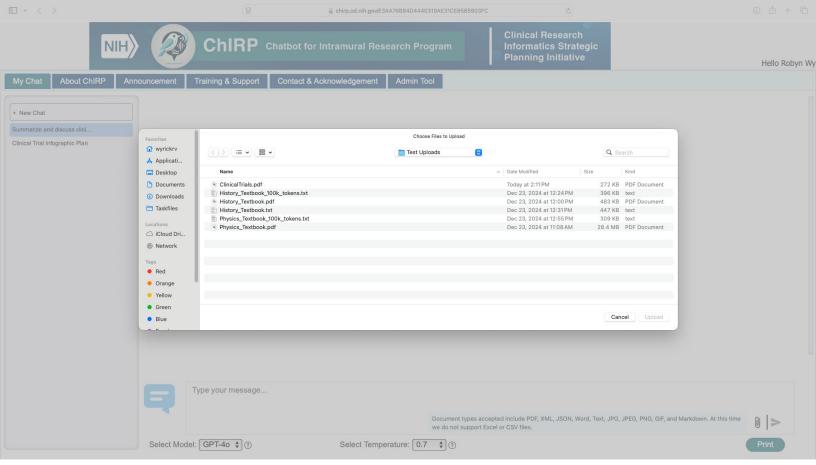
### Phase 4

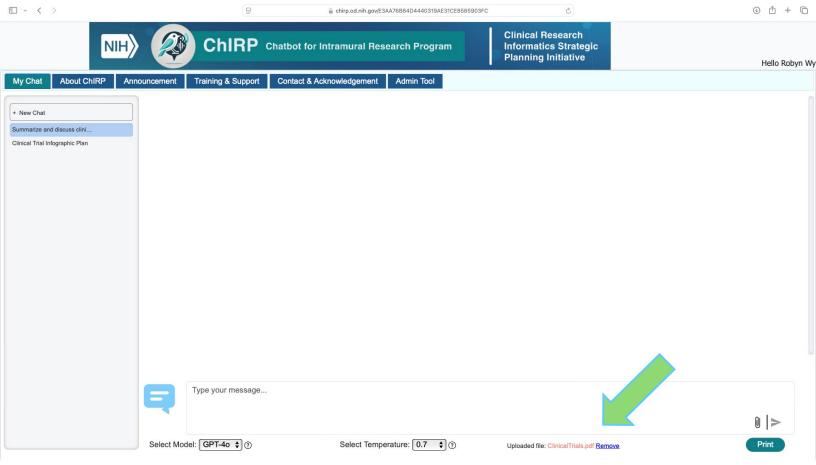
Phase 4 trials take place after the treatment has been approved for use by the FDA. These studies continue testing the treatment to collect information about its effects in various populations and any side effects associated with long-term use.

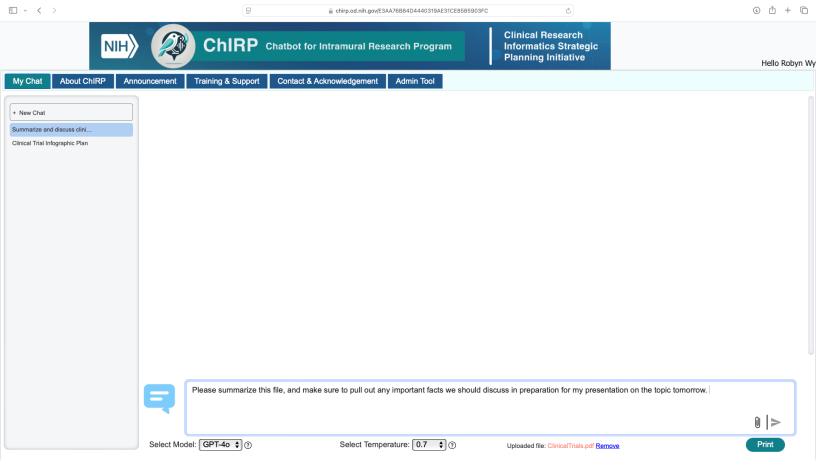
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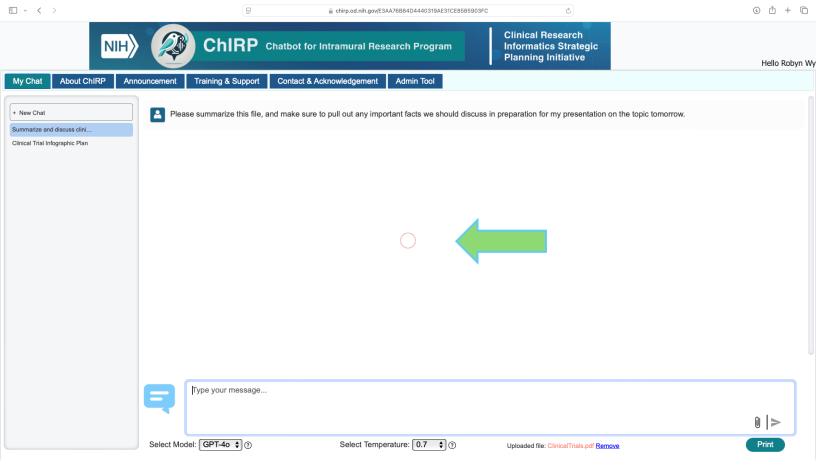
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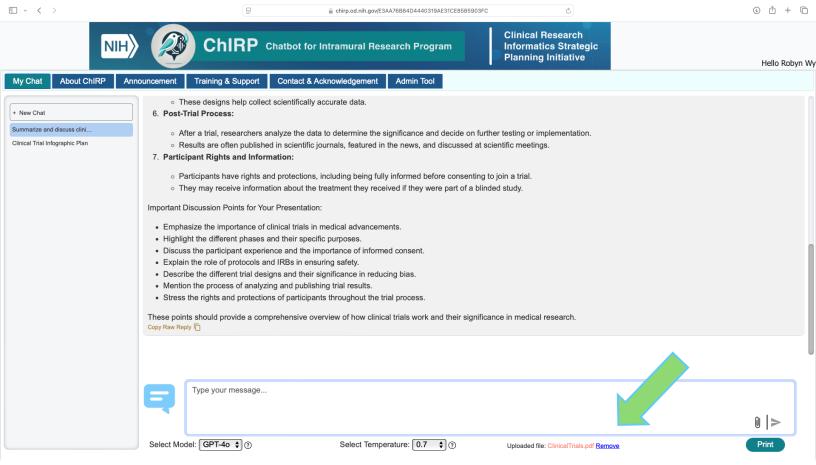








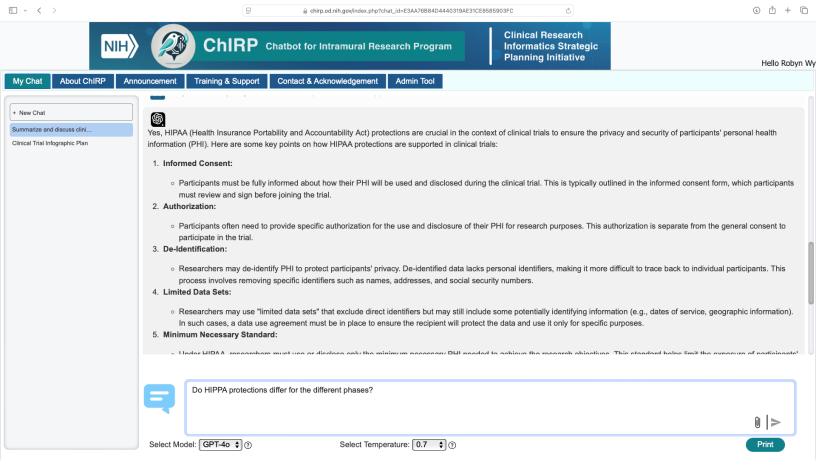




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	Clinical Research Informatics Strategic Planning Initiative	Helio Robyn Wy
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+ New Chat Summarize and discuss clini, Clinical Trial Infographic Plan	<ul> <li>Trials may involve blinding (single or double) to prevent bias and randomization to assign treatments randomly.</li> <li>These designs help collect scientifically accurate data.</li> <li>Post-Trial Process: <ul> <li>After a trial, researchers analyze the data to determine the significance and decide on further testing or implementation.</li> <li>Results are often published in scientific journals, featured in the news, and discussed at scientific meetings.</li> </ul> </li> <li>Participant Rights and Information: <ul> <li>Participants have rights and protections, including being fully informed before consenting to join a trial.</li> <li>They may receive information about the treatment they received if they were part of a blinded study.</li> </ul> </li> <li>Important Discussion Points for Your Presentation: <ul> <li>Emphasize the importance of clinical trials in medical advancements.</li> <li>Highlight the different phases and their specific purposes.</li> <li>Discuss the participant experience and the importance of informed consent.</li> <li>Explain the role of protocols and IRBs in ensuring safety.</li> <li>Describe the different trial designs and their significance in reducing bias.</li> <li>Mention the process of analyzing and publishing trial results.</li> <li>Stress the rights and protections of participants throughout the trial process.</li> </ul> </li> <li>These points should provide a comprehensive overview of how clinical trials work and their significance in medical research.</li> </ul>	
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Summarize and discuss clini, Clinical Trial Infographic Plan	<ul> <li>Yes, HIPAA (Health Insurance Portability and Accountability Act) protections are crucial in the context of clinical trials to ensure the privacy and security of participants' personal healt information (PHI). Here are some key points on how HIPAA protections are supported in clinical trials:</li> <li>Informed Consent: <ul> <li>Participants must be fully informed about how their PHI will be used and disclosed during the clinical trial. This is typically outlined in the informed consent form, which participants must review and sign before joining the trial.</li> <li>Authorization: <ul> <li>Participants often need to provide specific authorization for the use and disclosure of their PHI for research purposes. This authorization is separate from the general conserparticipate in the trial.</li> </ul> </li> <li>De-Identification: <ul> <li>Researchers may de-identify PHI to protect participants' privacy. De-identified data lacks personal identifiers, making it more difficult to trace back to individual participants. process involves removing specific identifiers such as names, addresses, and social security numbers.</li> </ul> </li> <li>Limited Data Sets: <ul> <li>Researchers may use "limited data sets" that exclude direct identifiers but may still include some potentially identifying information (e.g., dates of service, geographic information in such cases, a data use agreement must be in place to ensure the recipient will protect the data and use it only for specific purposes.</li> </ul> </li> <li>Minimum Necessary Standard:</li> </ul></li></ul>	ticipants eent to s. This
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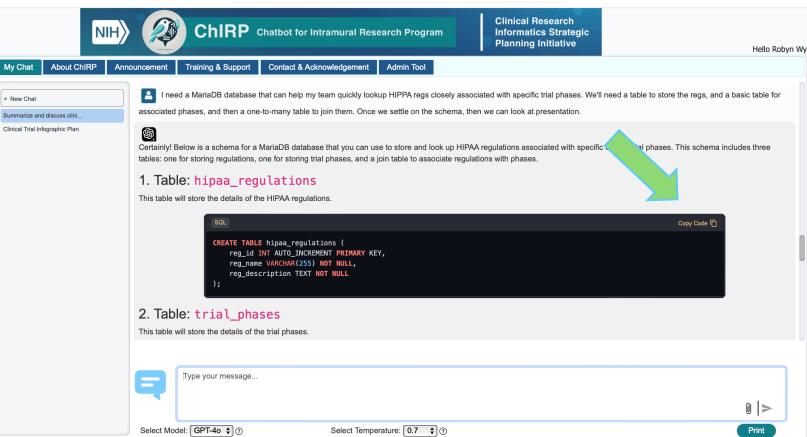


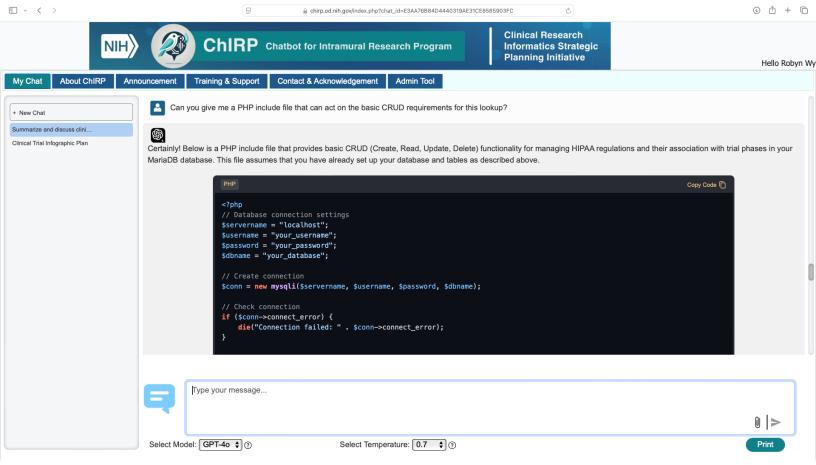
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	<ul> <li>Focus: Safety and dosage.</li> <li>HIPAA Protections: Since this phase involves a small number of participants and focuses on safety, PHI such as medical history and detailed health assessments are collect and protected. Informed consent and authorization for PHI use are critical at this stage.</li> <li>Phase II:</li> </ul>	эd
	<ul> <li>Focus: Efficacy and side effects.</li> <li>HIPAA Protections: More participants are involved, and researchers collect detailed health data to evaluate the treatment's effectiveness. Protection measures, including de- identification and secure data handling, are emphasized to manage the increased volume of PHI.</li> <li>Phase III:         <ul> <li>Focus: Confirmation of effectiveness, monitoring side effects, and comparison with standard treatments.</li> <li>HIPAA Protections: This phase involves a large number of participants, so robust data security measures are crucial. Researchers ensure that PHI is used and disclosed only necessary purposes, maintaining rigorous adherence to the minimum necessary standard.</li> </ul> </li> </ul>	
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+ New Chat	Please draft an email announcement to the team about the new application. We'll launch on January 23rd. This will be a real game changer for them.	
Summarize and discuss clini, Clinical Trial Infographic Plan	Sectainly! Below is a draft email announcement to your team about the new application launch:	
	Subject: Exciting News! New HIPAA Regulation Lookup Application Launching Soon! Dear Team,	
	I am thrilled to announce that we will be launching our new HIPAA Regulation Lookup Application on [Launch Date]!	
	This new application is designed to streamline our workflow and provide quick and easy access to HIPAA regulations associated with specific clinical trial phases. Here features that you can look forward to:	e are some of the key
	<ul> <li>Efficient Data Retrieval: Quickly look up HIPAA regulations related to various trial phases, making your research and compliance tasks faster and more efficient.</li> <li>User-Friendly Interface: Intuitive design to ensure that you can navigate and utilize the application with ease.</li> <li>Comprehensive Database: Access a robust database of HIPAA regulations and trial phases, all in one place.</li> </ul>	
	Secure and Reliable: Built with security in mind to protect sensitive information and ensure reliable performance.	
	We believe this application will be a real game changer for our team, enhancing our ability to manage and comply with HIPAA regulations effectively. We encourage you to familiarize yourself with the application once it goes live. Training sessions and support materials will be provided to help you get started and manew tool	ike the most out of this
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+ New Chat	I should have mentioned that this is the NHLBI Clinical Trials Communications Team. We'll begin training on January 12.	
Summarize and discuss clini Clinical Trial Infographic Plan	<ul> <li>So tit! Here's the revised email announcement tailored for the NHLBI Clinical Trials Communications Team, including details about the training:</li> <li>Subject: Exciting News! New HIPAA Regulation Lookup Application Launching Soon!</li> <li>Dear NHLBI Clinical Trials Communications Team,</li> <li>I am thrilled to announce that we will be launching our new HIPAA Regulation Lookup Application on [Launch Date]!</li> <li>This new application is designed to streamline our workflow and provide quick and easy access to HIPAA regulations associated with specific clinical trial phases. Here are features that you can look forward to:</li> <li>Efficient Data Retrieval: Quickly look up HIPAA regulations related to various trial phases, making your research and compliance tasks faster and more efficient.</li> <li>User-Friendly Interface: Intuitive design to ensure that you can navigate and utilize the application with ease.</li> <li>Comprehensive Database: Access a robust database of HIPAA regulations and trial phases, all in one place.</li> <li>Secure and Reliable: Built with security in mind to protect sensitive information and ensure reliable performance.</li> <li>We believe this application will be a real game changer for our team, enhancing our ability to manage and comply with HIPAA regulations effectively.</li> <li>To ensure that everyone is well-prepared to use the new application, we will begin training on [Training Start Date]. Training sessions will provide an overview of the application.</li> </ul>	
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# Thank you

- Robyn Wyrick
  - Al Integration Specialist, (Contractor)
  - National Heart, Lung, and Blood Institute (NHLBI)
  - National Institutes of Health (NIH)
  - Mobil: 202-374-4747
  - E-mail: robyn.wyrick@nih.gov