|  |  |  |  |
| --- | --- | --- | --- |
| **Main Topic:** Phases of Clinical Trials  **Learning Objectives/Outcomes:** | | | |
| **Topic 1:** Phase I | **Topic 2:** Phase II | **Topic 3:** Phase III | **Topic 4:** Phase IV |
| **Ideas**  **What happens in Phase I of clinical trials?**  **How big is the test group in Phase I?**  **What is the objective of Phase I?**  **Where do human test participants come from?**  **How are test subjects rewarded by participating in clinical trials?**  **What challenges are researchers face with in recruiting participants for clinical trials?** | **Ideas**  **What happens in Phase II of clinical trials?**  **How big is the test group in Phase II?**  **What is the objective of Phase II?** | **Ideas**  **What happens in Phase III of clinical trials?**  **How big is the test group in Phase III?**  **What is the objective of Phase III?**  **What happens after a product or procedure passes Phase III trials?**  **List what researchers must include in the documentation of new medical products and procedures.**  **What is this collection of information called?**  **Why is it provided?**  **If the product or procedure passes its FDA review, what then happens?** | **Ideas**  **What happens in Phase IV of clinical trials?**  **What information do researchers seek in Phase IV of clinical trials?**  **Describe the size and duration of Phase IV of clinical trials.** |
| **Key Vocabulary**  **Phase I:** | **Key Vocabulary**  **Phase II:** | **Key Vocabulary**  **Phase III:**  **Regulatory Submission:** | **Key Vocabulary**  **Phase IV:** |
| **Pictures** | **Pictures** | **Pictures** | **Pictures** |