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| **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** |