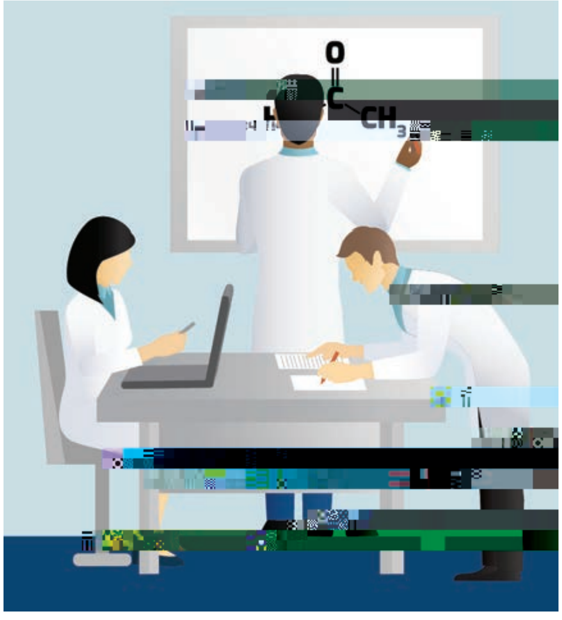
WHY DO RESEARCHERS DO DIFFERENT KINDS OF CLINICAL STUDIES?



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Observational Studies

In many studies, researchers do not do experiments or test new treatments; they observe. Observational studies help researchers understand a situation and come up with hypotheses that can be put to the [LZ[PU JSPUPJHS [YPHSZ 6IZLY]H[PVU associations between things but can't prove that one thing causes another. Types include:

Case Study/Case Series

A detailed description of one or more patients. By documenting new and unusual cases, researchers start to generate hypotheses about causes or risk factors.

Ecological Study

Compares the rate of a disease or condition for groups of people, such HZ [V^UZ PU KP\LYLU[JSPTH[LZ VY ^P[O KP\LYLU[average incomes.

Cross-Sectional Study

A snapshot of many people at one moment in time. These studies can show how common a condition is and help identify factors associated with it.

Case-Control Study

A group of people who have a condition is compared to a control group of people who don't. Possible causes or risk factors can emerge.

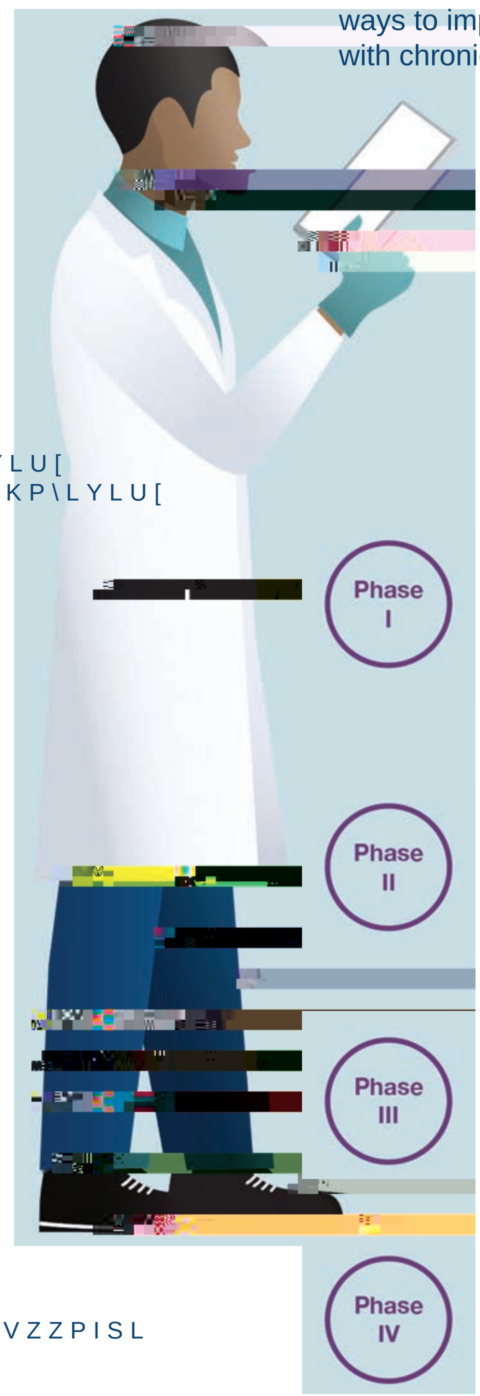
Cohort Study

A large group of people is observed over time. Some eventually develop a disease or condition. Researchers can learn how often the condition VJJ\YZ HUK ÄUK WVZZPISL causes or risk factors.

Clinical Trials

In these studies, researchers test new ways to prevent, detect, or treat disease. Treatments might be new drugs or combinations of drugs, new surgical procedures or devices, or new ways to use existing treatments. Clinical trials can also test other aspects of care, such as ways to improve the quality of life for people with chronic illnesses.

A well-designed clinical trial is the gold standard for proving that a treatment or medical approach works, QatiILa3bmds9 -2.4 Td (A wel28.1(trials are conducted in phases:



Phase I

- Purpose: Find out whether a medical approach (e.g., drug, diagnostic test, KL]PJL PZ ZHML PKLU[PM` HUK ÄN\YL V\[HWWYVWYPH[
- Number of people: Typically fewer than 100

Phase II

- Purpose: Start testing whether a medical approach works. Continue TVUP[VYPUN MVY ZPKL LMLJ[information that goes into designing a large, phase III trial.
- Number of people: Typically 100-300

Phase III

- Purpose: Prove whether a medical approach works; continue monitoring ZPKL LMLJ[Z
- Number of people: As many as needed or able to enroll—can be 1,000 or more

Phase IV

- Purpose: When a medical approach is being marketed, continue gathering PUMVYTH[PVU VU P[Z LMLJ[Z
- Number of people: Thousands

How good are these kinds of studies at showing cause and effect?

The strength of a study depends on its size and design. New results may con rm earlier ndings, contradict them, or add new aspects to scientists' understanding. In the end, cause and effect are usually hard to establish without a well-designed clinical trial.