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"Spot the crap" reporters' quiz: **Breakthrough Drug Trial**

Brainlink is produced by the Center for Mental Health and Media at Massachusetts General Hospital, and is distributed in partnership with the National Press Foundation. Brainlink is funded through a Science Education Drug Abuse Partnership Award from the National Institute on Drug Abuse. Its content does not necessarily represent the views of NIDA or the National Institutes of Health. For more information, go to <http://brainlink.org/about>.

A few years ago, a participant in a Phase III clinical trial of a new drug contacted a television medical reporter in a major American city. The government-funded research was being conducted at several well-respected medical centers around the country and involved more than 2000 participants.

The man had been suffering from a debilitating disease for years, and was stunned by the fact that soon after taking the pills given to him by the researchers, his symptoms essentially disappeared. He called it "a miracle."

The reporter verified the man's story (He really did have the disease and was participating in the research study that was evaluating a new drug.) and interviewed him about what had happened. That interview formed the core of a news report on how this "breakthrough" treatment could help tens of thousands of people.

Spot the crap.

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There are a bunch of both scientific and ethical problems with this conclusion. Here are two of the scientific issues:

Phase III clinical trials are double-blind. Neither the patient nor the researchers know yet whether the man actually received the new drug or, depending upon the research design, either a placebo or the standard treatment for the disease. That won't be revealed until the end of the study when they "crack the code" to see who got what.

Even if the man did receive the new drug, we can't generalize from a single case. That's why Phase III studies use lots of people. There are many reasons why his symptoms may have gotten better that have nothing to do with the new drug.

If you cover medicine in your reporting, you're sure to run across researchers talking about the "phases" of a clinical trial. Here's a quick rundown:

Phase 0 is the first exposure of humans to a new drug. It usually involves a dozen or so healthy people and a very small amount of the drug. Its purpose is

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to study how the body processes the drug (pharmacokinetics) and how it works in the body (pharmacodynamics.)

Phase I trials usually involve under 100 healthy people who receive the drug while staying in a hospital. This helps assess its safety at different doses. Occasionally, Phase I trials will use people at the final stage of an incurable disease.

Phase II trials involve several hundred subjects and begin to assess how well a drug works. They also continue to assess how safe it is. Many new drugs are discontinued during Phase II trials because they're either ineffective or have significant side effects.

Phase III trials usually involve thousands of subjects and are conducted at several research centers simultaneously. These are the classic double-blind trials (neither the subjects nor the researchers know who received the experimental or the control treatment before the trial is finished) that allow researchers to see if a new approach is better than the older ones.

Phase IV trials are also known as post-marketing surveillance. They take place after a drug is made available to the public to look for rare or long-term effects that may not have come to light earlier.