

# Clinical Trials Overview

Clinical trials are a form of medical research that test new developments in preventing, detecting, or treating a disease.

These trials use human volunteers to determine if a drug or technology is effective and safe. While some clinical trials test new treatments<sup>1</sup>, others compare existing treatments to show which may benefit patients more, or determine if an existing drug can be used to treat other diseases or conditions.<sup>2,3</sup>

Clinical trials are often sponsored by drug or medical device companies, federal agencies or private individuals with a medical background, like a physician.<sup>4</sup> Clinical trials are performed with strict rules and regulations set by the U.S. Food and Drug Administration (FDA) to ensure the safety of trial participants, however there are also risks associated with experimental treatments.<sup>5,6</sup>

Clinical trials follow a defined study plan, or protocol, and include elements such as different type of patients involved, study length and study outcomes.<sup>7</sup>

## THERE ARE SEVERAL KINDS OF TRIALS, INCLUDING:

- ▶ How to prevent certain diseases.
- ▶ New treatments or new ways to use existing treatments.
- ▶ New screening and diagnostic techniques.
- ▶ Options for improving quality of life in people who have medical conditions.<sup>8</sup>

The length of a clinical trial is outlined in the study plan<sup>9</sup> and is dependent on the treatment and medical condition being studied. Clinical trials may be conducted in multiple phases (often three), with each phase being defined by the FDA and seeking to answer a specific set of questions.<sup>10</sup>

## CLINICAL TRIAL PARTICIPATION

There are two types of volunteers who participate in clinical trials. **Healthy volunteers** have no known significant health problems. **Patient volunteers** have a known health problem that typically applies to the clinical trial. Some patient volunteers may benefit from clinical trial participation by having the opportunity to try a new treatment. Others serve as controls and do not receive the experimental treatment or take a different dose of treatment.<sup>11</sup> In some cases, volunteers will not know if they are receiving the designated trial treatment or serving as a control, so they can describe what happens without bias.<sup>12</sup>

Controls help researchers by providing important information on how the experimental treatment compares to others.<sup>13</sup>

Clinical trials are conducted using scientific methodology with carefully written instructions.<sup>14</sup> The instructions include rules on who can participate (e.g. gender, race, age, type and length of disease and treatment history) and how the treatment is provided (e.g. dose and frequency of treatment).<sup>15</sup> In some cases, trial participants may receive payment for participation, reimbursement for transportation or lost time from work.<sup>16</sup>

Visit <http://www.nih.gov/health/clinicaltrials/basics.htm>, the National Institutes of Health website, for more details on clinical trials.



## ENDNOTES

- 1 NIH Clinical Trials Research and You. What are clinical trials and why do people participate? National Institutes of Health. October 2012. <<http://www.nih.gov/health/clinicaltrials/basics.htm>>. Accessed November 5, 2013.
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- 5 Clinical Trials and Human Subject Protection. U.S. Food and Drug Administration. <<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm>>. Accessed November 5, 2013.
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- 14 About Clinical Trials: Key Messages and Why Clinical Trials are Important. August 2011. <<http://www.cancer.net/all-about-cancer/clinical-trials/about-clinical-trials>>. Accessed November 8, 2013.
- 15 Learn About Clinical Studies. Who participates in a clinical study? ClinicalTrials.gov. <<http://clinicaltrials.gov/ct2/info/understand>> Accessed November 5, 2013.
- 16 Basic Questions and Answers about Clinical Trials. Why are Clinical Trials Done? U.S. Food and Drug Administration. <<http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/hivandaidsactivities/ucm121345.htm>>. Accessed November 5, 2013.