

## **What is a clinical trial protocol?**

Every clinical trial has a carefully designed plan that provides complete details on the conduct of the trial. The protocol is written by the physician or sponsor and is provided to all the physicians involved. The protocol provides details on the:

- justification for conducting the study
- types of people needed to answer the question being studied
- number of people needed to answer the question being studied
- schedule of tests and procedures involved in the study
- medications and/or medical devices involved
- length of the study
- plan for analyzing the data produced
- guidelines and rules for stopping the study

The purpose of the clinical trial protocol is to ensure that the study is justified, that the entire trial is safe for the participants of the study, and that the study is designed to allow the research questions to be answered.