

PATIENT SAFETY



When a patient finds a potential clinical trial to participate in, a series of data points about the patient are collected at the beginning such as: age, race, and gender.



Another set of requirements are needed based on the patient's disease, medical history, and current health.

These requirements are part of the **inclusion criteria** and **exclusion criteria**.



INCLUSION CRITERIA ensure the participants in the study are medically similar.



EXCLUSION CRITERIA ensure the participants are kept safe by excluding them from the study due to the treatment possibly having a negative impact on the patient's health.



A protocol is written based on the inclusion and exclusion criteria, which also includes a written description of the trial and has a set of rules the patient must follow during the clinical trial.



Protocols would be requested for approval by the Institutional Review Board (IRB) to ensure patient safety and patient rights. Once approved, the Data Safety Monitoring Board (DSMB) will monitor the study throughout the clinical trial.