

Monitoring Patient Safety in Clinical Trials*

*BEFORE THE TRIAL BEGINS

Develops a plan for how safety will be monitored during the study

Approves the study before it begins based on the study protocol

Provides guidance on safety reporting

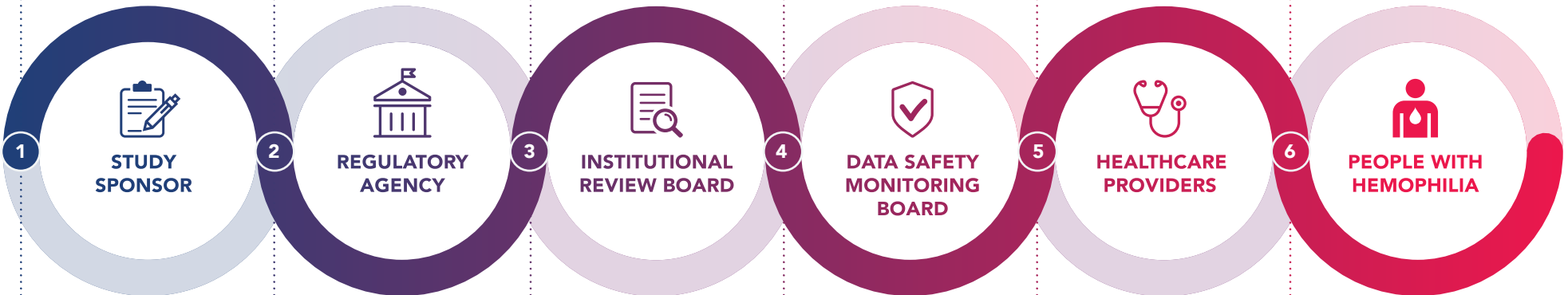
Reviews the study to evaluate possible benefits and risks

Approves the study to be conducted at a specific hospital

Makes a plan to monitor safety data during the study

Assesses patient eligibility to confirm it is safe to participate in the study

Learns as much as possible about the study plan, including potential risks and benefits



Reviews safety and side effects on a regular basis
Receives ongoing updates about the safety of the study

Provides general oversight and monitoring at research site

Monitors all study data; takes action if a safety risk is found

Conducts close monitoring of participant health
Reports adverse events to sponsor and regulatory agency

Follows the study plan and report any possible side effects and or concerns at each study visit

*DURING THE TRIAL