Monitoring Patient Safety in Clinical Trials*

WFH
WORLD FEDERATION OF HEMOPHILIA
FÉDÉRATION MONDIALE DE L'HÉMOPHILIE
FEDERACIÓN MUNDIAL DE HEMOFILIA

*BEFORE THE TRIAL BEGINS

1 **STUDY SPONSOR**

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

2 **REGULATORY AGENCY**

- Approves the study before it begins based on the study protocol
- Provides guidance on safety reporting

3 **INSTITUTIONAL REVIEW BOARD**

- Reviews the study to evaluate possible benefits and risks
- Approves the study to be conducted at a specific hospital

4 **DATA SAFETY MONITORING BOARD**

- Makes a plan to monitor safety data during the study

5 **HEALTHCARE PROVIDERS**

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

6 **PEOPLE WITH HEMOPHILIA**

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

*DURING THE TRIAL

1 **STUDY SPONSOR**

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

2 **REGULATORY AGENCY**

3 **INSTITUTIONAL REVIEW BOARD**

- Provides general oversight and monitoring at research site

4 **DATA SAFETY MONITORING BOARD**

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

5 **HEALTHCARE PROVIDERS**

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

6 **PEOPLE WITH HEMOPHILIA**

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