



## **SAEM Response to Request for Information: FDA-NIH Resource on Terminology for Clinical Research**

**Notice Number: NOT-OD-24-112**

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-112.html>

### **Confounding**

The suggested definition is: “Systematic error in estimation of the measure of the effect of a medical product on an outcome due to another factor that is associated with both the exposure and the outcome and not through the causal pathway between exposure and outcome.”

We suggest that the definition should be expanded to include interventions that may not qualify as “medical products.” A more comprehensive definition is required. We suggest that the wording be as follows: “Systematic error in estimation of the measure of the effect of a medical **intervention or other exposure** on an outcome due to another factor that is associated with both the exposure and the outcome and not through the causal pathway between exposure and outcome.”

### **Interventional Study**

The suggested definition is: “A study involving participants (e.g., healthy individuals or individuals with a disease or condition of interest) whose exposure or interaction with a medical product is assigned according to a study protocol to evaluate the effect on health outcomes or product performance.”

We suggest that the definition should be expanded to include interventions that may not qualify as “medical products.” A more comprehensive definition is required. We suggest that the wording be as follows: “A study involving participants (e.g., healthy individuals or individuals with a disease or condition of interest) whose exposure or interaction with a medical product or **intervention** is assigned according to a study protocol to evaluate the effect on health outcomes or product performance.”

### **Non-interventional (observation) study**

The suggested definition is: “A type of study in which individuals are not assigned to a medical product according to a protocol.”

Response: We suggest that the definition should be expanded to include interventions that may not qualify as “medical products.” A more comprehensive definition is required. We suggest that the wording be as follows: “A type of study in which individuals are not assigned to a medical product or **intervention** according to a protocol.”

### **Umbrella Trial**

The suggested definition is: “Trial designed to evaluate multiple medical products in separate sub-studies concurrently for a single disease or condition.”

Response: We suggest that the definition should be expanded to include interventions that may not qualify as “medical products.” A more comprehensive definition is required. We suggest that the wording be as follows: “Trial designed to evaluate multiple medical **interventions** in separate sub-studies concurrently for a single disease or condition.”