

## SAFETY OVERSIGHT

### KEY LEARNINGS

The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.

- Evaluate importance of quality with regards to safety
- Safety related responsibilities
- Importance of safety reporting
- Awareness about safety reporting timelines
- Safety related protocol requirements

### Adverse Event

- Any untoward medical occurrence in a patient/subject administered an Investigational Product (IP).
- Event does not necessarily have a causal relationship to the treatment.

### Serious Adverse Event

#### Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (ADR) Definition

Any untoward medical occurrence that at any dose ...

Results in death

Is life-threatening

Requires inpatient hospitalization or prolongs hospitalization



Results in persistent or significant disability/incapacity

Is a congenital anomaly/birth defect

Other important medical events

***All SAE's should be reported immediately***