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

All SAE's should be reported immediately