Sponsor-Investigator IND Scenarios

Scenario 1: One Sponsor-Investigator

Dr. Jekyll holds an IND and is Principal Investigator of the protocol conducted under that IND. She is a "true" Sponsor-Investigator who both initiates and conducts a study.

Scenario 2: One Sponsor Plus One Investigator

Dr. Watson holds an IND.

Dr. Moreau, a colleague at the same institution, is Principal Investigator of the protocol conducted under Dr. Watson's IND.

Scenario 3: One Sponsor Plus Multiple Investigators

Dr. Zhivago holds an IND and is Principal Investigator of the protocol under that IND at his own institution.

Dr. Frankenstein and Dr. No, two researchers at separate academic research centers, are Principal Investigators of the protocol under Dr. Zhivago's IND at their respective institutions.

EXERCISE: SAFETY REVIEW AND REPORTING / SCENARIO 1

Dr. Jekyll determines that an adverse event is serious, unexpected, and related to the study drug.

Sponsor responsibilities include:

- Review drug safety and efficacy data as it is received
- Notify FDA of new safety/risk information
- Notify investigators of new safety/risk information
- Discontinue study if investigational product presents unreasonable and significant risk to subjects

What processes and procedures can Dr. Jekyll establish to make sure her Sponsor obligations are met?
What documentation does Dr. Jekyll need to prove that she has fulfilled her Sponsor obligations?

EXERCISE: SAFETY REVIEW AND REPORTING / SCENARIO 2

Dr. Moreau determines that an adverse event is serious, unexpected, and related to the study drug.

Sponsor responsibilities include:

- Review drug safety and efficacy data as it is received
- Notify FDA of new safety/risk information
- Notify investigators of new safety/risk information
- Discontinue study if investigational product presents unreasonable and significant risk to subjects

What processes and procedures can Dr. Watson have in place to make sure her Sponsor obligations are met?
What documentation does Dr. Watson need to prove that she has fulfilled her Sponsor obligations?

EXERCISE: SAFETY REVIEW AND REPORTING / SCENARIO 3

Dr. No determines that an adverse event at his site is serious, unexpected, and related to the study drug.

Sponsor responsibilities include:

- Review drug safety and efficacy data as it is received
- Notify FDA of new safety/risk information
- Notify investigators of new safety/risk information
- Discontinue study if investigational product presents unreasonable and significant risk to subjects

What processes and procedures can Dr. Zhivago have in place to make sure his Sponsor obligations are met?
What documentation does Dr. Zhivago need to prove that he has fulfilled his Sponsor obligations?