

# US RAC Review Questions RAPS Modules 2022 with complete solution

In which situation is an IND not required?

- A) You intend to conduct a clinical trial with an investigational new drug
- B) You intend to conduct a clinical trial with an approved drug to support a marketing application for a new indication
- C) You intend to collect blood samples from subjects to look for biomarkers or pharmacogenetic information
- D) You intend to conduct a clinical trial using 2 of your approved drugs in a new combination Answer- C) You intend to collect blood samples from subjects to look for biomarkers or pharmacogenetic information

In the clinical development plan for an investigational antihypertensive drug, which of the following studies would typically be conducted first:

- A) 1 month repeat dose toxicology study
- B) Single dose escalation PK study in healthy volunteers
- C) Multiple dose PK study in healthy volunteers
- D) Single dose escalation study in hypertensive patients Answer- B) Single dose escalation PK study in healthy volunteers

A sponsor must report an unexpected, fatal or life-threatening experience believed to be associated with an unapproved drug/biologic:

- A) to FDA, investigators and IRBs within 7 calendar days
- B) to FDA and investigators within 7 calendar days
- C) to FDA within 14 calendar days
- D) to FDA and investigators within 7 working days Answer- B) to FDA and investigators within 7 calendar days

Which of the following is a covered study as defined under Financial Disclosure regulations:

- A) Phase I dose escalation study
- B) Phase I/II Pharmacokinetic Study
- C) A large open label safety study conducted at a large number of study sites
- D) Phase III pivotal study Answer- D) Phase III pivotal study

# Raps Rac Exam Questions

**Elijah Wreh**



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