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39	A	B	C	D	E

PRACTICE QUESTIONS

ACRP - Association of Clinical Research Professionals

QXGUBUVC

ACRP-Medical Device Professional

EDITION

Demo

QUESTIONS

9

FORMAT

Limited Edition PDF

Before you begin

What this is

9 practice questions for ACRP - Association of Clinical Research Professionals QXGUBUVC , each with its answer key and an explanation. Answer a question before you read its key — the explanation is worth more once you have committed.

If something looks wrong

Send us three things and we will check it:

- the exam code, QXGUBUVC
- the question number
- the email address on your order

Write to **support@mometrix.net**. We reply within one business day.

QUESTION 1

SINGLE CHOICE

A sponsor is designing a clinical investigation for a Class III implantable cardiac device intended to support a PMA submission. Which trial design element is most appropriate to prospectively control for confounding patient variables and to support a valid scientific comparison?

- ☐ A A single-arm study with historical controls
- ☒ B A randomized, controlled trial with concurrent controls
- ☐ C A case series with descriptive outcomes only
- ☐ D A post-market registry without a predefined hypothesis

ANSWER B

WHY For a Class III implantable supporting a PMA, a randomized controlled trial with concurrent controls is the most rigorous design to minimize bias and support a valid scientific comparison. Single-arm/historical control designs, descriptive case series, and post-market registries are weaker designs and would generally not be sufficient as the primary support for a PMA for this device class.

QUESTION 2

SINGLE CHOICE

Under FDA regulations, which party bears the ultimate regulatory responsibility for the conduct of a medical device clinical investigation, including IND/IDE submission, monitoring oversight, and adverse event reporting?

- ☐ A The investigator
- ☐ B The IRB
- ☒ C The sponsor
- ☐ D The contract research organization (CRO)

ANSWER C

WHY The sponsor holds ultimate regulatory responsibility for the clinical investigation under 21 CFR Part 812, including IDE submission, selection of qualified monitors, and evaluation of unanticipated adverse device effects. Investigators, IRBs, and CROs have defined responsibilities but the sponsor's obligations cannot be transferred, only delegated in writing for specific tasks.

QUESTION 3 SINGLE CHOICE

An investigator is enrolling subjects in an IDE study and a previously enrolled subject experiences an unanticipated adverse device effect (UADE). Within how many working days must the investigator submit a report of the UADE to the sponsor and the IRB?

- ☐ A Within 24 hours
- ☐ B Within 5 working days
- ☒ C Within 10 working days
- ☐ D Within 30 working days

ANSWER C

WHY Under 21 CFR 812.150(b)(1), an investigator must submit a report of an unanticipated adverse device effect to the sponsor and the IRB within 10 working days of learning of the effect. This is shorter than the 30-day reporting window for significant risk device studies' annual progress reports and is distinct from the 24-hour sponsor reporting clock.

QUESTION 4 SINGLE CHOICE

Which document is the primary written agreement between the sponsor and the investigator that defines the responsibilities, financial arrangements, and scope of work for a medical device clinical investigation?

- ☐ A The Informed Consent Form
- ☐ B The Investigator's Brochure
- ☒ C The Clinical Trial Agreement (or Investigator Agreement)
- ☐ D The IDE application

ANSWER C

WHY The Clinical Trial Agreement (also called the Investigator Agreement or CTA) is the contractual document between the sponsor and investigator/institution that defines responsibilities, deliverables, publication rights, and financial arrangements. The Informed Consent Form is the document given to subjects, the Investigator's Brochure summarizes device and pre-clinical data, and the IDE application is the regulatory submission to FDA.

QUESTION 5 SINGLE CHOICE

A sponsor wishes to market a novel, moderate-risk device for which there is no legally marketed predicate device. The device has no previously established classification. Which regulatory pathway is most appropriate?

- ☐ A Premarket Notification [510(k)]
- ☐ B Premarket Approval (PMA)
- ☒ C De Novo classification request
- ☐ D Humanitarian Device Exemption (HDE)

ANSWER C

WHY The De Novo classification request under section 513(f)(2) of the FD&C Act is the standard pathway for novel, low-to-moderate risk devices that have no predicate and no existing classification. A 510(k) requires a predicate; a PMA is for high-risk Class III devices; an HDE is reserved for humanitarian use devices intended for rare diseases/conditions.

QUESTION 6 SINGLE CHOICE

Which of the following elements must be included in an informed consent document for a medical device clinical investigation under 21 CFR Part 50?

- ☐ A A statement that the device may be a Class III device
- ☐ B A statement that the sponsor will publish the results regardless of outcome
- ☒ C A statement that the study involves research, the purposes of the research, the procedures, and reasonably foreseeable risks
- ☐ D A statement that the investigator is exempt from negligence liability

ANSWER C

WHY Under 21 CFR 50.25, the informed consent must begin with a statement that the study involves research, explain its purposes, describe the procedures, identify reasonably foreseeable risks or discomforts, describe anticipated benefits, alternative treatments, confidentiality protections, compensation/medical treatment for injury, contact information, and the voluntary nature of participation. Publishing outcomes, device classification, and waiver of liability are not required elements.

QUESTION 7

SINGLE CHOICE

During routine monitoring at an investigator site, the clinical research coordinator cannot locate two investigational devices that were previously logged in the device accountability log. The investigator does not know what happened to them. What is the most appropriate next action?

- ☐ A Document the loss in the case report form and continue enrollment
- ☒ B Reconcile the discrepancy immediately, document it on the device accountability log, and report it to the sponsor
- ☐ C Discard the device accountability log entries and start a new log
- ☐ D Wait until the next monitoring visit to address the issue

ANSWER B

WHY Investigational device accountability under 21 CFR 812.140 requires a complete and accurate device accountability record at the site. Any discrepancy must be investigated and reconciled promptly, documented in the accountability log, and communicated to the sponsor, who must then assess potential impact on subject safety and data integrity. Ignoring, hiding, or delaying the resolution of a discrepancy is a serious GCP compliance issue.

QUESTION 8

SINGLE CHOICE

A subject enrolled in an IDE study develops a serious adverse event that the investigator determines is unanticipated and definitely related to the investigational device. This best meets the definition of which event category?

- ☐ A Anticipated adverse device effect
- ☐ B Serious adverse event (SAE) only
- ☒ C Unanticipated adverse device effect (UADE)
- ☐ D Device deficiency

ANSWER C

WHY An Unanticipated Adverse Device Effect (UADE) is defined under 21 CFR 812.3(s) as any serious adverse effect on health or safety, or any life-threatening problem or death, associated with a device, where the effect was not previously identified in nature, severity, or degree of incidence in the investigational plan, or other current materials. The fact that it is serious, unanticipated, and device-related makes it a UADE, triggering both investigator (10 working days) and sponsor (10 working days to FDA and all reviewing IRBs) reporting obligations.

QUESTION 9

MULTIPLE CHOICE

Which of the following are core responsibilities of an Institutional Review Board (IRB) reviewing a significant risk medical device investigation under 21 CFR Part 56? (Choose two.)

- ☒ **A** Reviewing the informed consent document and ensuring it contains the required 21 CFR Part 50 elements
- ☐ **B** Conducting statistical analysis of the primary endpoint
- ☒ **C** Approving the protocol and ensuring risks to subjects are minimized and reasonable in relation to anticipated benefits
- ☐ **D** Marketing the investigational device to hospitals

ANSWER A • C

WHY Under 21 CFR Part 56, the IRB's core responsibilities include reviewing and approving the protocol, reviewing and approving the informed consent to ensure it contains the required elements of 21 CFR 50.25, and ensuring that risks to subjects are minimized and reasonable in relation to anticipated benefits. Statistical analysis is the responsibility of the sponsor/biostatistician, and marketing an unapproved investigational device is prohibited.