一、 請您將下列這段英文敘述，逐字翻譯成中文，期能忠實呈現其意涵 (20%)。

【摘錄自 Catania, C. (2012). Clinical trial nurse's role in safety reporting. *Nursing Forum, 47*(1), 18-26.】

A clinical trial is defined as a research study involving human participants that is intended to answer specific health questions about how to improve health and control or cure disease. Clinical trials are conducted in order to determine the safety of the investigational agent and to understand adverse events (AEs) associated with the intervention. A multidisciplinary clinical research team is involved in the conduct of clinical trials that includes determining the safety of an investigational drug or device. One important member of the multidisciplinary research team is the clinical trial nurse (CTN). The CTN performs many duties, one of which includes gathering information and reporting serious adverse events.

Although risks in clinical trials are inevitable, safety reporting allows for risks to be minimized and for unanticipated harms to be rapidly detected and contained. It is the efforts and collaboration of the CTN and the principal investigator (PI) in the assessment and reporting of AEs that allow the subject's rights and well-being to be protected. The roles and responsibilities of the CTN in safety reporting are critical to the conduct of clinical trials. The CTN is an integral part of the safety reporting process. The CTN is well suited for the development of AEs and/or serious events because of his or her nursing background and his or her knowledge in disease processes. The CTN is also well suited for this role because he or she receives research-specific training. This includes having an adequate understanding of clinical research, research ethics, and the components of Good Clinical Practices (GCP). This understanding allows the CTN to ensure the probity and safety of the research process. This is particularly true for the CTN who is familiar with the GCP guidelines, which cover all aspects of clinical trials including AEs reporting. The CTN acquires knowledge relating to clinical trials, regulations, and guidance by participating in educational opportunities. The CTN is able to utilize this knowledge and experience and integrate it with the roles of safety reporting.

Although regulatory documents do not refer to the CTN in the safety reporting process, they still have a significant part to play in this role by assisting and collaborating with the investigator. However, the nurse can serve as the PI if he or she is appropriately prepared at the doctoral level and paired with a physician for pharmaceutical clinical trials. In this case, the nurse as the PI is permitted to assume the leadership role. Regardless of the role, the CTN is involved and contributes to the assessment, documentation, and reporting of AEs.

見背面

二、請詳閱下列這段敘述之後，依據其意回答所列之問題：

【摘錄自Choi, J.C. et al. (2014) 發表於 Patient Preference and Adherence, 8: 167-177. 文章】

Abstract

【**Background**】Oral dabigatran was recently approved as an alternative to warfarin for prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. Unlike warfarin, dabigatran has a fixed dosage and few drug interactions, and does not require anticoagulation monitoring or dietary restrictions.

【**Methods**】This study aimed to describe and compare characteristics of patients with atrial fibrillation who used dabigatran or only warfarin. Patients with a self-reported diagnosis of atrial fibrillation aged ≥18 years who were receiving (or had received) warfarin or dabigatran completed an online survey. Differences in characteristics of dabigatran and warfarin users were tested using chi-squared tests and analysis of variance for categorical and continuous variables, respectively.

【**Results**】Overall, 364 patients were surveyed (204 warfarin users, 160 dabigatran users). The mean age was 65.1 years, and 68.7% were male. Dabigatran users were more likely than warfarin users to be female (36.9% versus 27.0%) and to have experienced adverse events, including gastrointestinal bleeding, in the 3 months before the survey (21.9% versus 6.9%; $p<0.05$). Both groups reported high medication adherence (dabigatran users 0.65 versus warfarin users 0.63 missed doses/month). Dabigatran users were more likely than warfarin users to discuss treatment options with their physician before beginning therapy (36.9% versus 24.5%; $p<0.05$) and less likely to switch anticoagulant medication (10.7% versus 31.9%; $p<0.05$). Although dabigatran users were more likely to experience adverse events, they reported greater satisfaction with anticoagulation treatment than warfarin users.

【**Conclusion**】 The efficacy and convenience reported by dabigatran users resulted in greater treatment satisfaction among dabigatran users, even though adverse events decreased it. Treatment strategies that minimize adverse events may improve treatment satisfaction and adherence among patients with atrial fibrillation.

1. 依據上文，此研究最有可能是哪一種類型之研究設計？試述此種研究設計的優點及缺點。(10%)
2. 請寫出其所使用到之統計方法及其對應的變項類別。(5%)
3. 由此摘要得知此研究結果有哪些發現？您將如何應用這些研究結果於臨床護理此類患者，請寫出您可能的照護計畫及其相關立論依據。(15%)

接次頁

三、請試著從進階護理實務(Advanced Nursing Practice; APN) 的護理專業角色拓展觀點，敘述將 CRN 的護理教育程度提升至碩士層級，CRN 所需具備的護理能力為何(15%)? 並說明「臨床研究護理師(Clinical research nurse; CRN) 」與「臨床護理專家(Clinical nursing specialist; CNS) 」角色職責的異同點(15%)。

四、當 CRN 在醫院執行臨床試驗/研究的過程中，當發生「應該由誰給予住院受試者試驗用藥」，以及「雙方如何配合抽血時間點」等情況時，您將會採取哪些符合「優良藥品臨床試驗規範(Good Clinical Practice Guideline; GCP」且適切的因應策略，來避免與臨床護理人員 RN (Registered Nurse; RN)發生衝突 (20%)?

試題隨卷繳回