姓 名： 編號：

證書郵寄：地址□□□□□

1. **是非題**(每題10分) 下面觀念如果您認為正確，請寫(O)。如果您認為不正確，請寫(X)：

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| --- | --- |
| (O) | 1.多區域藥物臨床試驗中，區域間差異性(regional differences)的來源主要是族群因素(ethnic factors)，根據ICH E5或是E17，族群因素(ethnic factors)又分為內在因子與外在因子兩種(intrinsic and extrinsic factors)。 |
| (X) | 2.100% data verification is preferred FDA |

1. **選擇題**(每題2.5分)

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| (C) | 1.關於Region的敘述，以下何者為是?(A) Region could be a geographical region, country or regulatory region (B) Regulatory region refers to a region for which a common set of regulatory requirements applies for drug approval (e.g., European Union)(C)以上皆是 |
| ( D ) | 2.關於E17的敘述，以下何者為是?(A)相對於independent strategy, 採用E17 MRCT有助於simultaneous drug development(B) E5 approach為sequential，E17 approach為parallel(C)不論是驗證性試驗(confirmatory trial)或是探索性試驗(exploratory trial)，均可採用MRCT的方式來執行(D)以上皆是 |
| ( B ) | 3.降血糖藥臨床試驗，試驗主要療效指標為「自基礎值至治療6個月糖化血色素(HbA1c)改變值」，試驗唯一相關的「並發事件(intercurrent event) 」為服用急救藥物(rescue medication)，請問以下Estimand分別採用何種並發事件處理策略:將主要療效指標改為二分法結果，療效反應者(responder)定義為HbA1c下降超過某一特定的閥值(threshold)，且無服用急救藥物者(A) treatment policy strategy(B) composite strategy(C) hypothetical strategy(D) principal stratum strategy(E) while on treatment strategy |
| ( B ) | 4. \_\_\_\_means a situation where the demonstration of treatment effects on all of two or more distinct endpoints is necessary to establish clinical benefit. (A) Multiple primary endpoints (B) Co-primary endpoints (C) Alternative primary endpoints (D) Primary and secondary endpoints  |
| ( D ) | 5. What is true about risk based monitoring in ICH E6 R2(A) The sponsor should develop a systematic, prioritized, risk-based approach to monitoring clinical trials. (B) The sponsor may choose on-site monitoring, a combination of on-site and centralized monitoring, or, where justified, centralized monitoring. (C) The sponsor should document the rationale for the chosen monitoring strategy (e.g., in the monitoring plan).(D) All of the above. |
| ( D ) | 6. What are the important areas can be overseen remotely(A) Number of protocol deviation occurred(B) Number of AE / SAE in relation to other sites(C) Enrollment at your site(D) All of the above |
| ( D ) | 7.Benefits could be gained by implementing RBM(A) Reduce monitoring costs(B) Improve data quality(C) Improve quality oversight(D) All of the above |
| ( A ) | 8.請問ICH E6 R2中提到的 Quality management system涵蓋哪些部分? (1) Critical Process and Data Identification(2) Risk Identification(3) Risk Evaluation(4) Risk Control(5) Risk Communication(6) Risk Review.(7) Risk Reporting(A) 以上皆是(B) (2),(3),(4)(C) (1),(2),(3),(4),(5),(6) |