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) |