107 年度藥品臨床試驗品質精進及權益維護教育計畫

進階研習班(一)-前測

姓　　名：＿＿＿＿＿＿＿＿＿＿　　編號：＿＿＿＿＿＿＿＿＿＿

一、 是非題(每題 7 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)：

(X) 1. Phase 1 clinical study may include patients?

(O) 2. Phase 2 study may not use doses outside the dose range tested in phase 1?

(O) 3. Proof of Concept studies may use surrogate biomarker as clinical end point?

(O) 4. The selection of a minimum phase 2 clinical dose should be based on clinical efficacy?

(O) 5. The selection of a maximum phase 2 clinical dose is usually based on safety?

二、 選擇題(每題 7 分)

(C) 1. 針對國內 BE 試驗相關法規，請問「藥品生體可用率及生體相等性試驗準則」於哪一年提升為「準則」位階？

(A)2007

(B)2008

(C)2009

(D)2010

(D) 2. 常見學名藥 BE 試驗設計，為 single dose、crossover design，除了特殊考量之外，一般在受試藥品與對照藥品兩次投藥間的 wash-out period 至少應有多久時間？

(A) 2 個排除半衰期

(B) 3 個排除半衰期

(C) 4 個排除半衰期

(D)5 個排除半衰期

(D) 3. 若 BE 試驗設計，必須為多劑量試驗，在進行藥動連續採樣前，通常應採幾個 Ctrough，以確認該受試者血中藥物濃度已達穩態濃度？

(A)不用採

(B)1 個

(C)2 個

(D)3 個

(A) 4. 以下何種 formulation 變更，已涉及主要變更？

(A) Starch 增加 12%

(B) Mg Stearate 增加 0.3%

(C) Talc 減少 1.5%

(D) batch size 增加 8 倍

(B) 5. 某廠商的「低劑量控釋劑型」之生體相等性試驗已通過，在同廠牌「高劑量控釋劑型」具有「配方賦形劑相似」的情況下，廠商想根據 98.12.31 衛署藥字第 0980364804 號公告，進行「口服固體製劑高低單位含量 biowaiver」，請問應執行哪一種試驗？

(A)溶離率曲線比對

(B)生體相等性試驗

(C)不用執行任何試驗

(D)溶離率曲線比對或生體相等性試驗二則一即可

三、 問答題(每題 6 分)

1. What would be the choice of study population for non-oncology first-in-human trials?

Answer: Usually healthy volunteers in phase 1a SAD (single ascending dose) studies; Can still be healthy volunteers or may consider patients with mild degree target disease in phase 1b MAD (multiple ascending dose) studies

2. What would be considered for the calculation of the safe starting dose in a FIH study?

Answer: Nonclinical data package submitted to regulatory authorities, including PK (pharmacokinetics), PD (pharmacodynamics), TK (toxicokinetics) and toxicological profiles

3. A dose escalation study design (single or multiple ascending dose study) is designed to identify the maximum tolerated dose. True or False?

Answer: True

4. Is data and safety monitoring board (DSMB) needed in a first-in-human study? Why?

Answer: Usually not needed

5. Please list three key elements in writing a FIH study protocol.

Answer: Any three of the followings: study population; nonclinical data; starting dose selection; dose escalation rule; stopping rules for individual subjects (safety), a given dose cohort (dose suspension) and the entire study (early termination); interim analysis