

附錄 4 - 臨床試驗年度進度報告

收件日期: 檔案編號:

Appendix 4 –Clinical Trial Yearly Progress Report

報告期 Report period	至 to		
本報告日期 Date of this report (dd-mm-yyyy) :			
臨床證驗證明書編號 CTMT cert no. :			
試驗方案編號 Protocol No. :			
試驗方案名稱 Protocol Title :			
開始日期 Start date :	日Day	月Month	年Year
預計結束日期 Anticipated end date :	日Day	月Month	年Year

目標病人數目(試驗方案所載) Target no. of patient (as stated in protocol)	
擬招募病人數目(每個地點) No of patient intend to recruit (per site)	
已招募病人數目(每個地點) No of patient recruited (per site)	
完成試驗的病人數目(每個地點) No. of patient completed the trial (per site)	
退出試驗的病人數目(每個地點) No. of patient drop-out from study (per site)	
退出原因 Reasons for drop-out :	

研究方案/研究者有否改變?(如有, 請提供詳情) Any changes for study protocol/ investigator? (If yes please give details)	
報告期內所作修訂的撮要 (如有, 請提供) Summary of amendments during report period (if any)	

嚴重不良事故的撮要 (如有, 請提供) Summary of Serious Adverse Events (if any)	
嚴重不良事故有否影響研究? 有何影響及採取的行動? Does SAE affect the study? How and what action has been taken?	
針對研究所提出的投訴撮要 (如有, 請提供) Summary of complaints from subject about the study (if any)	

近期研究結果的撮要 (特別是關於研究所涉風險的資料)

Summary of recent findings (especially information about risks associated with the research)

試驗藥物的用藥紀錄 (如多於 1 種試驗藥物，請另頁填寫)：

Record of usage of the investigational product (If more than 1 investigational product, please use a separate sheet):

試驗藥物名稱 Name of investigational product			
供應單位及地址 Name and address of supplier			
收貨數量 Quantity received		日期 Date	
使用後的餘額 Remaining quantity after use		日期 Date	

研究進度 Progress of study

- 按計劃進行 According to Plan
- 研究期延長 Extend study period (原因 reason _____)
- 中途結束 Premature termination (原因 reason _____)

研究者姓名 Name of Investigator :

簽署 Signature :

職位 Posting :

日期 Date :

機構名稱及地址 Name and Address of Organization :

如空位不敷填寫，請另頁詳列有關資料，並在有關部份註明。負責人須在該頁上註明其姓名和簽署，然後將附頁釘夾在此報告；如對填寫以上資料有任何查詢，可於辦公時間致電衛生署查詢，電話：3904 9130。

If there is insufficient space, please use a separate sheet and indicate accordingly in the relevant part of the Report. The responsible person should write his name and sign on the attached sheet, and attach it to the report; if you have any enquiries when filling in the above information, please contact the Department of Health at 3904 9130.