第8章之附表

8.2 臨床試驗開始前(Before the Clinical Phase of the Trial Commences)				
	Title of Document 文件標題	Purpose 目的	Located in Files of 文件保存地點	
			Investigator/ Institution 試驗主持人/ 試驗機構	Sponsor 試驗委託者
8.2.1	INVESTIGATOR'S BROCHURE 主持人手冊	To document that relevant and current scientific information about the investigational product has been provided to the investigator 紀錄有關試驗藥品之相關、最新科學資訊已提供給試驗主持人	X	X

8.2.2	SIGNED PROTOCOL AND AMENDMENTS, IF ANY, AND SAMPLE CASE REPORT FORM (CRF) 經簽名的試驗計畫書及其變更版本（若有）與個案報告表範本	To document investigator and sponsor agreement to the protocol/amendment(s) and CRF 紀錄試驗主持人和試驗委託者皆同意試驗計畫書及其變更版本與個案報告表之內容	X	X
8.2.3	INFORMATION GIVEN TO TRIAL SUBJECT 提供予受試者的資訊			
	- INFORMED CONSENT FORM (including all applicable translations) - 受試者同意書（包含所有適用的翻譯）	To document the informed consent 紀錄受試者告知後同意過程	X	X

	- ANY OTHER WRITTEN INFORMATION - 其他書面資訊	To document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent 紀錄受試者將收到適當的書面資訊（內容及措詞），以支持他們給予充分告知後同意之能力	X	X
	- ADVERTISEMENT FOR SUBJECT RECRUITMENT (if used) - 受試者招募廣告（若有）	To document that recruitment measures are appropriate and not coercive 紀錄招募方法適當且無壓迫性	X	
8.2.4	FINANCIAL ASPECTS OF THE TRIAL 試驗之財務狀況	To document the financial agreement between the investigator/institution and the sponsor for the trial 紀錄試驗主持人/試驗機構和試驗委託者間與試驗相關之財務協議	X	X
8.2.5	INSURANCE STATEMENT (where required) 保險聲明（必要時）	To document that compensation to subject(s) for trial-related injury will be available 紀錄將提供受試者試驗相關傷害之補償	X	X

8.2.6	SIGNED AGREEMENT BETWEEN INVOLVED PARTIES, e.g.: - investigator/institution and sponsor - investigator/institution and CRO - sponsor and CRO - investigator/institution and authority(ies) (where required) 經相關當事人簽名之協議，例如： - 試驗主持人/試驗機構和試驗委託者 - 試驗主持人/試驗機構和受託研究機構 - 試驗委託者和受託研究機構 - 試驗主持人/試驗機構和主管機關（必要時）	To document agreements 紀錄協議內容	 X X X	 X X (where required) (若需要) X X

8.2.7	DATED, DOCUMENTED APPROVAL/FAVOURABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB) /INDEPENDENT ETHICS COMMITTEE (IEC) OF THE FOLLOWING: - protocol and any amendments - CRF (if applicable) - informed consent form(s) - any other written information to be provided to the subject(s) - advertisement for subject recruitment (if used) - subject compensation (if any) - any other documents given approval/ favourable opinion 載明日期之IRB/IEC書面核准內容如下： - 試驗計畫書及任何變更版本 - 個案報告表（若適用）	To document that the trial has been subject to IRB/IEC review and given approval/favourable opinion. To identify the version number and date of the document(s) 紀錄試驗計畫已經IRB/IEC審查並核准，以及指明文件之版本編號與日期	X	X

	- 受試者同意書 - 任何其他提供給受試者的書面資料 - 受試者招募廣告（若有） - 受試者損害補償（若有） - 任何其他獲得核准之文件			
8.2.8	INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE COMPOSITION IRB/IEC的組成	To document that the IRB/IEC is constituted in agreement with GCP 紀錄IRB/IEC的組成符合GCP	X	X (where required) (若需要)
8.2.9	REGULATORY AUTHORITY(IES) AUTHORISATION/APPROVAL/NOTIFICATION OF PROTOCOL (WHERE REQUIRED) 主管機關對試驗計畫書的授權/核准/通知(必要時)	To document appropriate authorisation/approval/notification by the regulatory authority(ies) has been obtained prior to initiation of the trial in compliance with the applicable regulatory requirement(s) 紀錄於試驗開始之前已依照相關法規獲得主管機關之適當授權/核准/通知	X (where required) (若需要)	X (where required) (若需要)

8.2.10	CURRICULUM VITAE AND/OR OTHER RELEVANT DOCUMENTS EVIDENCING QUALIFICATIONS OF INVESTIGATOR(S) AND SUB-INVESTIGATOR(S) 試驗主持人和協同試驗主持人之簡歷及/或證明其資格的其他相關文件	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects 紀錄其執行試驗及/或督導受試者之醫療照護的資格及合適性	X	X
8.2.11	NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/ LABORATORY/TECHNICAL PROCEDURE(S) AND/OR TEST(S) INCLUDED IN THE PROTOCOL 試驗計畫書中醫學/實驗室/技術程序及/或檢驗的正常值及/或範圍	To document normal values and/or ranges of the tests 紀錄各項檢驗的正常值及/或範圍	X	X

8.2.12	MEDICAL/LABORATORY/TECHNICAL PROCEDURES /TESTS - certification or - accreditation or - established quality control and/or external quality assessment or - other validation (where required) 醫療/實驗室/技術程序/檢驗之 - 證書，或 - 認證，或 - 建立品質管制及/或外部品質評估，或 - 其他驗證（必要時）	To document competence of facility to perform required test(s), and support reliability of results 紀錄執行必要檢驗及支持檢驗結果可信度之設備能力	X (where required) (若需要)	X
8.2.13	SAMPLE OF LABEL(S) ATTACHED TO INVESTIGATIONAL PRODUCT CONTAINER(S) 試驗藥品之容器標籤樣本	To document compliance with applicable labelling regulations and appropriateness of instructions provided to the subjects 紀錄符合相關的標籤法規及提供給受試者的指示之適當性		X

8.2.14	INSTRUCTIONS FOR HANDLING OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS (if not included in protocol or Investigator's Brochure) 試驗藥品及試驗相關材料之處理說明 （若試驗計畫書或主持人手冊沒有提及）	To document instructions needed to ensure proper storage, packaging, dispensing and disposition of investigational products and trial-related materials 紀錄確保試驗藥品及試驗相關材料適當儲存、包裝、配發及處置所需之指示	X	X
8.2.15	SHIPPING RECORDS FOR INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS 試驗藥品及試驗相關材料之運送紀錄	To document shipment dates, batch numbers and method of shipment of investigational product(s) and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability 紀錄試驗藥品及試驗相關材料之運送日期、批號、運送方法，以追溯其批號、運送條件之檢查及權責	X	X

8.2.16	CERTIFICATE(S) OF ANALYSIS OF INVESTIGATIONAL PRODUCT(S) SHIPPED 已運送的試驗藥品之分析證明	To document identity, purity, and strength of investigational product(s) to be used in the trial 紀錄將用於臨床試驗之試驗藥品的特性、純度及濃度		X
8.2.17	DECODING PROCEDURES FOR BLINDED TRIALS 盲性試驗之解碼程序	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subjects' treatment 紀錄在緊急情況下，盲性試驗藥品如何解碼以揭示受試者身分，而不會破壞其他受試者之治療的盲性設計	X	X (third party if applicable) (若適用第三方)
8.2.18	MASTER RANDOMISATION LIST 隨機分配清單	To document method for randomisation of trial population 紀錄受試者群體隨機分配的方法		X (third party if applicable) (若適用第三方)

8.2.19	PRE-TRIAL MONITORING REPORT 試驗前之監測報告	To document that the site is suitable for the trial (may be combined with 8.2.20) 紀錄試驗場所執行試驗之合適性（可與8.2.20合併）		X
8.2.20	TRIAL INITIATION MONITORING REPORT 試驗開始之監測報告	To document that trial procedures were reviewed with the investigator and the investigator's trial staff (may be combined with 8.2.19) 紀錄試驗主持人及試驗人員已審閱試驗計畫書（可與8.2.19合併）	X	X

8.3 臨床試驗執行期間 (During the Clinical Conduct of the Trial)

	Title of Document 文件標題	Purpose 目的	Located in Files of 文件保存地點	
			Investigator/ Institution 試驗主持人/試驗機構	Sponsor 試驗委託者

8.3.1	INVESTIGATOR'S BROCHURE UPDATES 更新版主持人手冊	To document that investigator is informed in a timely manner of relevant information as it becomes available 紀錄相關資訊在可取得時及時提供給試驗主持人	X	X
8.3.2	ANY REVISION TO: - protocol/amendment(s) and CRF - informed consent form - any other written information provided to subjects - advertisement for subject recruitment (if used) 以下文件的任何修訂： - 試驗計畫書/變更版本及個案報告表 - 受試者同意書	To document revisions of these trial related documents that take effect during trial 紀錄在試驗期間生效的這些試驗相關文件之修訂	X	X

	- 任何其他提供給受試者的書面資料 - 受試者招募廣告（若有）			

8.3.3	DATED, DOCUMENTED APPROVAL/FAVOURABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB) /INDEPENDENT ETHICS COMMITTEE (IEC) OF THE FOLLOWING:
	- protocol amendment(s)
	- revision(s) of:
	  - informed consent form
	  - any other written information to be provided to the subject
	  - advertisement for subject recruitment (if used)
	- any other documents given approval/favourable opinion
	- continuing review of trial (where required)
	載明日期之IRB/IEC書面核准內容如下：
	- 試驗計畫書變更版本
	- 以下文件的修訂：
	  - 受試者同意書
		To document that the amendment(s) and/or revision(s) have been subject to IRB/IEC review and were given approval/favourable opinion. To identify the version number and date of the document(s).
		紀錄這些變更及/或修訂內容已經IRB/IEC審查及核准，並指明文件的版本編號及日期
			X	X

	- 任何其他提供給受試者的書面資料 - 受試者招募廣告（若有） - 任何其他已核准文件 - 試驗的持續審查（必要時）			
8.3.4	REGULATORY AUTHORITY(IES) AUTHORISATIONS/APPROVALS/NOTIFICATIONS WHERE REQUIRED FOR: - protocol amendment(s) and other documents 依法規要求主管機關對以下文件之授權/核准/通知： - 試驗計畫書變更版本或其他文件	To document compliance with applicable regulatory requirements 紀錄遵循相關法規要求	X (where required) (若需要)	X
8.3.5	CURRICULUM VITAE FOR NEW INVESTIGATOR(S) AND/OR SUB-INVESTIGATOR(S) 新的試驗主持人或協同試驗主持人的簡歷	(see 8.2.10) （參閱8.2.10）	X	X
8.3.6	UPDATES TO NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/ LABORATORY/ TECHNICAL PROCEDURE(S)/TEST(S) INCLUDED IN THE PROTOCOL	To document normal values and ranges that are revised during the trial (see 8.2.11)	X	X

	試驗計畫書中醫學/實驗室/技術程序/檢驗的正常值/範圍之更新	紀錄在試驗期間修訂的正常值及範圍（參閱8.2.11）		
8.3.7	UPDATES OF MEDICAL/LABORATORY/ TECHNICAL PROCEDURES/TESTS - certification or - accreditation or - established quality control and/or external quality assessment or - other validation (where required) 醫學/實驗室/技術程序/檢驗之更新 - 證書，或 - 認證，或 - 建立品質管制及/或外部品質評估，或 - 其它驗證（必要時）	To document that tests remain adequate throughout the trial period (see 8.2.12) 紀錄整個試驗期間內之檢驗皆適當（參閱8.2.12）	X (where required) (若需要)	X
8.3.8	DOCUMENTATION OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS SHIPMENT	(see 8.2.15) （參閱8.2.15）	X	X

	試驗藥品及試驗相關材料之運送紀錄			
8.3.9	CERTIFICATE(S) OF ANALYSIS FOR NEW BATCHES OF INVESTIGATIONAL PRODUCTS 新批次試驗藥品之分析方法證明	(see 8.2.16) （參閱8.2.16）		X
8.3.10	MONITORING VISIT REPORTS 監測訪視報告	To document site visits by, and findings of, the monitor 紀錄監測者的實地訪視及發現		X
8.3.11	RELEVANT COMMUNICATIONS OTHER THAN SITE VISITS - letters - meeting notes - notes of telephone calls 實地訪視之外的相關溝通紀錄 - 信函 - 會議紀錄	To document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event (AE) reporting	X	X

	- 電話會談紀錄	紀錄與試驗管理、違反試驗計畫書、試驗執行及不良事件報告有關的協議或重要討論		
8.3.12	SIGNED INFORMED CONSENT FORMS 經簽名的受試者同意書	To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each subject in trial. Also to document direct access permission (see 8.2.3) 紀錄在每位受試者參與試驗前，取得告知後同意的過程符合	X	

		GCP及試驗計畫書，並載明日期。同時紀錄受試者對直接檢視的許可（參閱8.2.3）		
8.3.13	SOURCE DOCUMENTS 原始文件	To document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of subject 紀錄受試者的狀態及證明所收集數據之完整性。收錄與試驗、	X	

		醫療及受試者病史相關的正本資料		
8.3.14	SIGNED, DATED AND COMPLETED CASE REPORT FORMS (CRF) 經簽名、載明日期且完整的個案報告表	To document that the investigator or authorised member of the investigator's staff confirms the observations recorded 紀錄試驗主持人或被授權的試驗人員確認所紀錄的觀察值	X (copy) (副本)	X (original) (正本)
8.3.15	DOCUMENTATION OF CRF CORRECTIONS 更正個案報告表之紀錄	To document all changes/additions or corrections made to CRF after initial data were recorded	X (copy) (副本)	X (original) (正本)

		紀錄在初始數據被紀錄之後，對個案報告表所做的所有變更/新增或更正		
8.3.16	NOTIFICATION BY ORIGINATING INVESTIGATOR TO SPONSOR OF SERIOUS ADVERSE EVENTS AND RELATED REPORTS 初始試驗主持人給試驗委託者之嚴重不良事件及相關報告之通知	Notification by originating investigator to sponsor of serious adverse events and related reports in accordance with 4.11 初始試驗主持人依4.11規定給試驗委託者之嚴重不良事件及相關報告之通知	X	X
8.3.17	NOTIFICATION BY SPONSOR AND/OR INVESTIGATOR, WHERE APPLICABLE, TO REGULATORY AUTHORITY(IES) AND IRB(S)/IEC(S) OF UNEXPECTED	Notification by sponsor and/or investigator, where applicable, to	X (where required) (若需要)	X

	SERIOUS ADVERSE DRUG REACTIONS AND OF OTHER SAFETY INFORMATION 試驗委託者及/或試驗主持人依法規要求向主管機關及IRB/IEC通報非預期藥品嚴重不良反應及其他安全性資訊	regulatory authorities and IRB(s)/IEC(s) of unexpected serious adverse drug reactions in accordance with 5.17 and 4.11.1 and of other safety information in accordance with 5.16.2 and 4.11.2 試驗委託者及/或試驗主持人依5.17及4.11.1規定向主管機關及IRB/IEC通報非預期藥品嚴重不良反應及依5.16.2及4.11.2規定通報其他安全性資訊		

8.3.18	NOTIFICATION BY SPONSOR TO INVESTIGATORS OF SAFETY INFORMATION 試驗委託者提供試驗主持人安全性資訊	Notification by sponsor to investigators of safety information in accordance with 5.16.2 試驗委託者依5.16.2規定提供試驗主持人安全性資訊	X	X
8.3.19	INTERIM OR ANNUAL REPORTS TO IRB/IEC AND AUTHORITY(IES) 檢送至IRB/IEC及主管機關之期中或年度報告	Interim or annual reports provided to IRB/IEC in accordance with 4.10 and to authority(ies) in accordance with 5.17.3 依4.10規定檢送至IRB/IEC以及依5.17.3規定檢送至主管機關之期中或年度報告	X	X (where required) (若需要)

8.3.20	SUBJECT SCREENING LOG 受試者篩選紀錄	To document identification of subjects who entered pre-trial screening 紀錄參加試驗前篩選程序之受試者的身分	X	X (where required) (若需要)
8.3.21	SUBJECT IDENTIFICATION CODE LIST 受試者身分代碼表	To document that investigator/institution keeps a confidential list of names of all subjects allocated to trial numbers on enrolling in the trial. Allows investigator/institution to reveal identity of any subject	X	

		紀錄試驗主持人/試驗機構製作一份應予保密、含有所有具試驗代碼之受試者姓名清單，使試驗主持人/機構得以辨識任何一位受試者		
8.3.22	SUBJECT ENROLMENT LOG 受試者納入紀錄	To document chronological enrolment of subjects by trial number 紀錄按試驗編碼依照時間順序納入受試者	X	
8.3.23	INVESTIGATIONAL PRODUCTS ACCOUNTABILITY AT THE SITE 在試驗中心的試驗藥品數量管理	To document that investigational product(s) have been	X	X

		used according to the protocol 紀錄試驗藥品是依據試驗計畫書使用		
8.3.24	SIGNATURE SHEET 簽名表	To document signatures and initials of all persons authorised to make entries and/or corrections on CRFs 紀錄所有被授權輸入及/或更正個案報告表者其簽名及姓名縮寫	X	X
8.3.25	RECORD OF RETAINED BODY FLUIDS/ TISSUE SAMPLES (IF ANY) 保存體液/組織樣本的紀錄（若有）	To document location and identification of retained samples if	X	X

		assays need to be repeated 若需要重複分析，紀錄所保存樣本之地點及樣本之辨識資料		

8.4 在試驗完成或終止後 (After Completion or Termination of the Trial)

	Title of Document 文件標題	Purpose 目的	Located in Files of 文件保存地點	
			Investigator/ Institution 試驗主持人/試驗機構	Sponsor 試驗委託者

8.4.1	INVESTIGATIONAL PRODUCT(S) ACCOUNTABILITY AT SITE 試驗藥品於試驗中心之數量管理	To document that the investigational product(s) have been used according to the protocol. To documents the final accounting of investigational product(s) received at the site, dispensed to subjects, returned by the subjects, and returned to sponsor 紀錄試驗藥品之使用符合試驗計畫書。紀錄試驗藥品於試驗中心之接收、發放給受試者、受試者退回及歸還給試驗委託者之最終數量	X	X
8.4.2	DOCUMENTATION OF INVESTIGATIONAL PRODUCT DESTRUCTION 試驗藥品之銷毀紀錄	To document destruction of unused investigational products by sponsor or at site 紀錄未使用之試驗藥品由試驗委託者或試驗中心銷毀	X (if destroyed at site) (若在試驗中心銷毀)	X

8.4.3	COMPLETED SUBJECT IDENTIFICATION CODE LIST 完整受試者身份代碼表	To permit identification of all subjects enrolled in the trial in case follow-up is required. List should be kept in a confidential manner and for agreed upon time 在需要後續追蹤時，使所有參與試驗之受試者身分可被辨識。代碼表應予保密並依約定時間保存	X	
8.4.4	AUDIT CERTIFICATE (if available) 稽核證書(1.7)（若有）	To document that audit was performed 紀錄已執行稽核		X
8.4.5	FINAL TRIAL CLOSE-OUT MONITORING REPORT 試驗結束監測報告	To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files 紀錄所有試驗結束之所需程序皆已完成，且必要文件之副本皆已適當歸檔		X
8.4.6	TREATMENT ALLOCATION AND DECODING DOCUMENTATION 治療分配及解碼紀錄	Returned to sponsor to document any decoding that may have occurred 交還試驗委託者以紀錄任何曾發生之解碼		X

8.4.7	FINAL REPORT BY INVESTIGATOR TO IRB/IEC WHERE REQUIRED, AND WHERE APPLICABLE, TO THE REGULATORY AUTHORITY(IES) 必要時試驗主持人向IRB/IEC以及法規要求時向主管機關提交結案報告	To document completion of the trial 紀錄試驗之完成	X	
8.4.8	CLINICAL STUDY REPORT 臨床試驗報告	To document results and interpretation of trial 紀錄試驗結果並提供解釋	X (if applicable) (若適用)	X