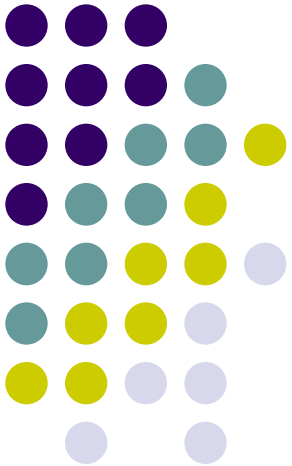
長庚醫院
臨床試驗計畫案登錄

Clinical Trial Registration



內容大綱

一、前言

二、登錄作業系統及步驟簡介

三、常見問題

四、注意事項

一、前言

（1）依據國際醫學雜誌編輯委員會（The International Committee of Medical Journal Editors,ICMJE）之投稿規定，臨床試驗研究計畫投稿者須於招募第一位受試者參與試驗前，將通過研究倫理委員會審核之臨床試驗計畫資料登錄於臨床試驗公開網站，完成登錄作業後，國際醫學雜誌編輯委員會（ICMJE）才會接受研究結果之發表。

WHO對臨床試驗研究計畫之定義為任何對受試者或特定族群進行一個或多個與健康有關的介入措施（如藥物、外科處置、器材、行為治療、飲食介入及照護過程改變）以評估對健康的效益之計畫，非屬上述臨床試驗計畫，請計畫主持人自行決定是否登錄。

（2）未完成臨床試驗登錄之計畫案，ICMJE有權不接受其文章發表

（3）由研究者自行發起之研究案（責任歸屬於PI者），應由計畫主持人於取得IRB同意函後完成登錄；若有廠商贊助之計畫，贊助者應主動完成紀錄。

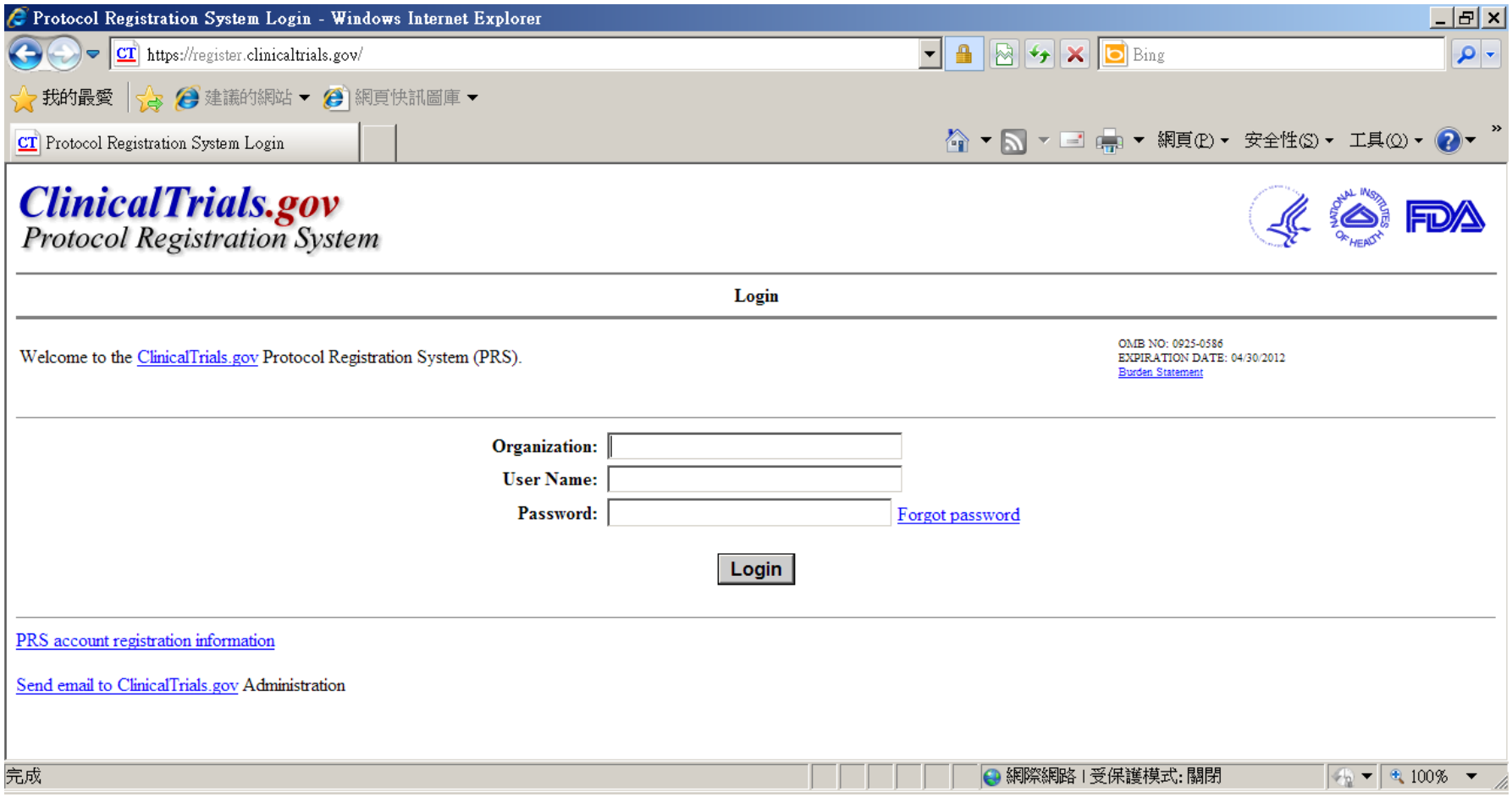
（4）林口長庚醫院已有美國國衛院（National Institutes of Health,NIH）之ClinicalTrails.gov網站－Protocol Registration system（PRS）本院專用帳號。

二、登錄步驟

請輸入下列網址：

http://register.clinicaltrials.gov

登入Protocol registration System 畫面



ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Main Menu

One or more of this organization's records requires administrator attention. Details...

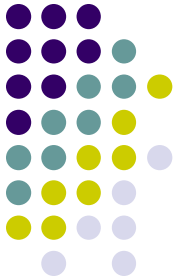
Our records show that your current email address is "mmtfuh@www.cmuh.org.tw, irb@www.cmuh.org.tw". If this is not correct, please update your account.

U.S. Public Law 110-85
About Results Data Entry...

點選
create

Standard Functions	Administrative Functions
Protocol Records	**Protocol Records**
Create	Check all records
Modify	Validate all records
QA Review Comments	Release all records
View	Check release status
Check my records	Change owner
Undelete	Publication Report
User Account	**User Accounts**
Change password	Create

當你選擇「Create」後，會出現以下畫面



ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Create New Protocol Record

To avoid duplicate or invalid registration of your study, check the following before proceeding with registration:

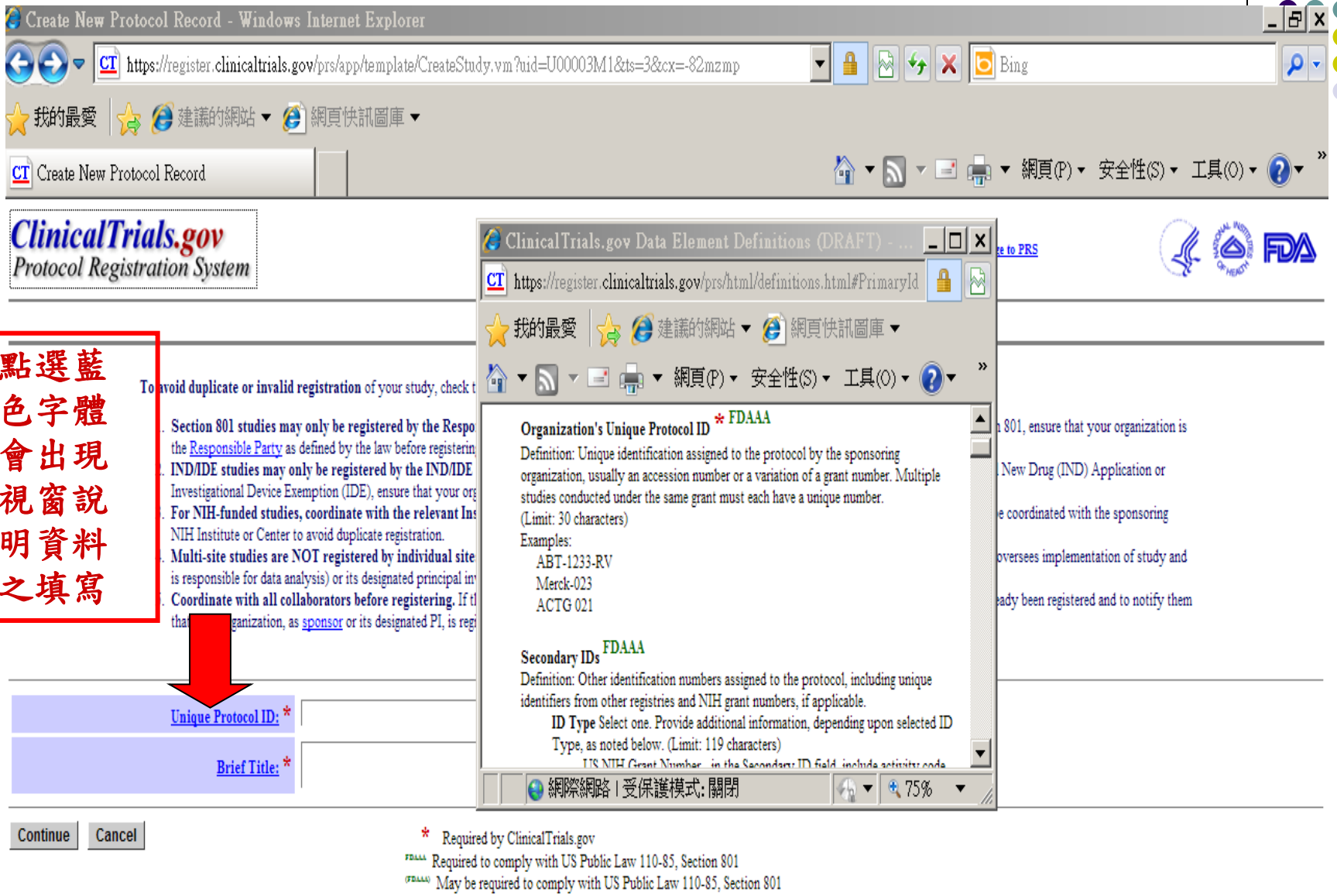
1. **Section 801 studies may only be registered by the Responsible Party.** If this is an applicable clinical trial as defined by US Public Law 110-85, Title VIII, Section 801, ensure that your organization is the Responsible Party as defined by the law before registering the study.
2. **IND/IDE studies may only be registered by the IND/IDE holder.** If the study is subject to US Food and Drug Administration regulations, under an Investigational New Drug (IND) Application or Investigational Device Exemption (IDE), ensure that your organization is the IND/IDE holder before registering the study.
3. **For NIH-funded studies, coordinate with the relevant Institute or Center.** If this is a US National Institutes of Health (NIH) funded study, registration should be coordinated with the sponsoring NIH Institute or Center to avoid duplicate registration.
4. **Multi-site studies are NOT registered by individual sites.** If this is a multi-site study it must be registered only once, by the sponsor (primary organization that oversees implementation of study and is responsible for data analysis) or its designated principal investigator (PI).
5. **Coordinate with all collaborators before registering.** If the study has multiple collaborators, contact the other organizations to confirm that the study has not already been registered and to notify them that your organization, as sponsor or its designated PI, is registering the study.

Unique Protocol ID: *

Brief Title: *

Continue Cancel

* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
(FDAAA) May be required to comply with US Public Law 110-85, Section 801



點選藍色字體會出現視窗說明資料之填寫

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links

Title: Astragalus Membranaceus for Brain Edema Induced by... ID: DMR96-IRB-126

Unique Protocol ID: * FDAAA	Enter sponsoring organization's unique identifier.
Brief Title: * FDAAA (Special characters)	Use lay language. Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer
Acronym:	If there is an acronym or abbreviation used to identify this study, enter it here.
Official Title:	Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate
Study Type: * FDAAA	Interventional Observational Expanded Access About expanded access records
FDA Regulated Intervention? (FDAAA)	Indicate whether this trial includes an intervention subject to US Food and Drug Administration regulations. --Select--
IND/IDE Protocol? * (FDAAA)	Indicate whether the protocol is subject to US Food and Drug Administration regulations, under an Investigational New Drug (IND) Application or Investigational Device Exemption (IDE). --Select--

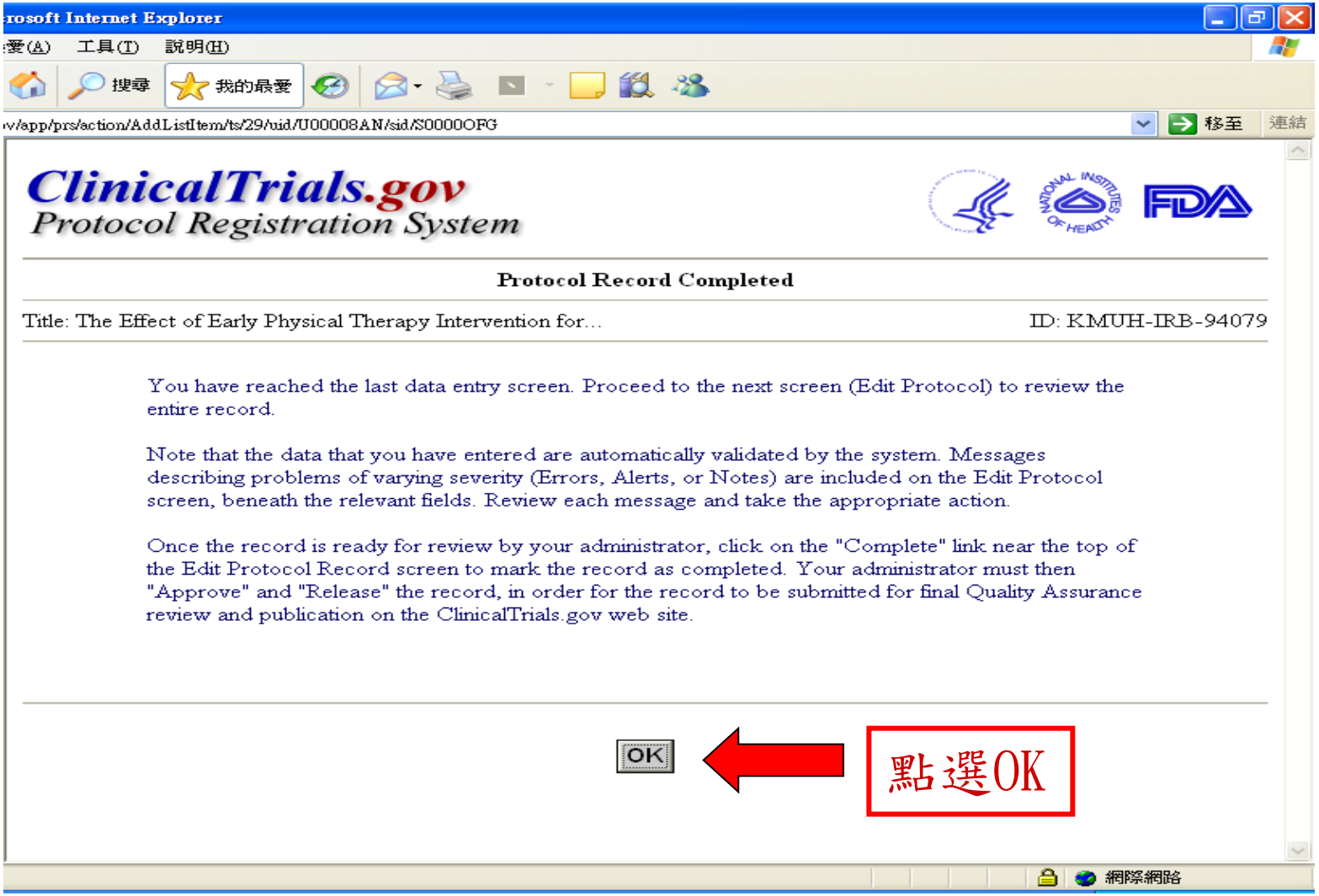
Continue Quit

* Required by ClinicalTrials.gov

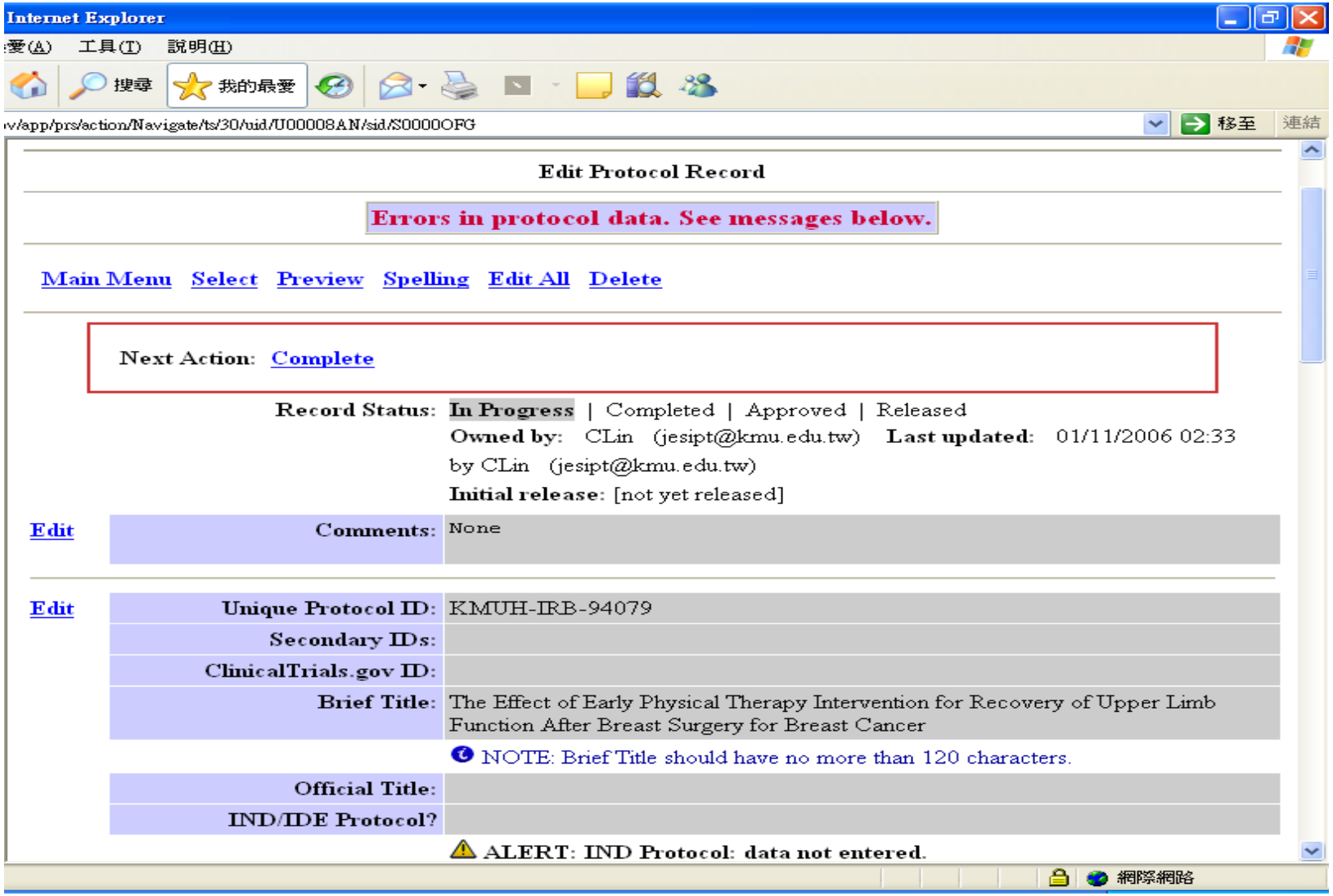
FDAAA Required to comply with US Public Law 110-85, Section 801

填完後選擇「continue」並按照指示將所需資料依序輸入

等所有資料輸入完成會出現以下畫面



當你點選「OK」後會出現以下畫面



詳細檢視您登錄的資料，如出現紅色字體為登入不完全, 如下:

	Collaborators:	
Edit	Review Board:	Approval Status: Approved Board Name: Board Affiliation:
		⚠ ALERT: Approval Number: data not entered. ⚠ ALERT: Board Name: data not entered. ⚠ ALERT: Board Affiliation: data not entered. ⚠ ALERT: Neither Board Phone nor Email was entered.
	Oversight Authorities:	
		⚠ ALERT: Oversight Authorities not entered.
Edit	Brief Summary:	
		ERROR: Brief Summary is a required field.
	Detailed Description:	
		NOTE: Detailed Description: data not entered.
Edit	Phase:	
		ERROR: Phase is a required field.
	Study Type:	Interventional
	Overall Status:	
		ERROR: Overall Status is a required field.
	Record Verification Date:	
		ERROR: Verification Date is a required field.
	Study Start Date:	
		NOTE: Study Start Date not entered.
	Last Follow Up Date:	

若無法當次完成登錄所有資料請勿按 Complete

請至畫面中的“**Main Menu**”點選 **Modify**可檢視你未編輯完成的案子,確定資料還存在你的帳號中

- 若要繼續編輯或修改案子，一樣在點選Modify進去之後，選擇Edit繼續編輯完成。
- 點選Logout即可登出此計畫案
- 若全部完成點選complete後，請等IRB 與ClinicalTrials 聯繫確認您的計劃案所有資料無誤, 數天後便可於ClinicalTrials網頁查詢到你登錄的計畫案

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Home Search Study Topics Glossary

Search

ClinicalTrials.gov is a registry of federally and privately supported clinical trials conducted in the United States and around the world. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and phone numbers for more details. This information should be used in conjunction with advice from health care professionals. Read more...

Search for Clinical Trials

點選查詢

Find trials for a specific medical condition or other criteria in the ClinicalTrials.gov registry. ClinicalTrials.gov currently has 88,453 trials with locations in 172 countries.

Investigator Instructions

Get instructions for clinical trial investigators/sponsors about how to register trials in ClinicalTrials.gov. Learn about mandatory registration and results reporting requirements and US Public Law 110-85 (FDAAA).

Background Information

Learn about clinical trials and how to use ClinicalTrials.gov, or access other consumer health information from the US National Institutes of Health.

Resources:

- Understanding Clinical Trials
- What's New
- Glossary

Study Topics:

- List studies by Condition
- List studies by Drug Intervention
- List studies by Sponsor
- List studies by Location

HON code CERTIFIED 03/2010

This site complies to the HONcode standard for trustworthy health information: verify here.

三、常見問題

Responsible Party

Responsible Party:	Name/Official Title: Organization: Phone: Ext: Email:

⚠ WARNING: Responsible Party Name/Official Title has not been entered.

⚠ WARNING: Responsible Party Organization has not been entered.

⚠ WARNING: Neither Responsible Party Phone nor Email was entered.

正確填寫的方式

- Name/Official Title：請填計畫主持人
- Organization：請填ChangGungMH
- Phone／E-mail：請填計畫主持人

Review Board

Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:


WARNING: Approval Status has not been entered.


ALERT: Board Name: data not entered.


ALERT: Board Affiliation: data not entered.


ALERT: Neither Board Phone nor Email was entered.

正確填寫的方式

- Approval Number ：請填IRB案件編號
- Board Name ：請填China Medical University Hospital Research Ethics Committee
- Board Affiliation ：請填China Medical University Hospital
- Phone ：請填計畫主持人
- E-mail ：請填計畫主持人

Oversight Authorities

Oversight Authorities:	

ALERT: Oversight Authorities not entered.

正確填寫的方式

- 此欄位請填

  Taiwan: Department of Health

Central Contact

- NOTE: Study Official is required by the WHO and ICMJE.

正確填寫的方式

- 此欄位請填計畫主持人或案件管理人資料

Study Officials/Investigators

- NOTE: Study Official is required by the WHO and ICMJE.

正確填寫的方式

- 此欄位請填計畫主持人的資料
- 如果有一個以上的計畫主持人，亦可無限新增

Brief Summary

Detailed Description

Record Verification Date

Overall Status

Study Start Date

Primary Completion Date

Study Completion Date

正確填寫的方式

- Brief：1200個字元限制
- Detail Description：2500個字元限制
- Record verification data:第一次登錄時間以取得IRB核准函上的日期為主（只需登錄到月份即可），若有修改則以修改日為主

Overall Status

Overall Status:	Recruiting
	ERROR: At least one Location needs to be recruiting if the Overall Status of the study is Recruiting.

Overall Status

Locations:	
	ERROR: At least one Location needs to be specified if the Overall Status of the study is Recruiting.

正確填寫的方式

- Overall status：此欄位為必填，因登錄的時間點是在第一位受試者收案前，所以在欄位上請填『Recruiting』。

填寫內容中出現不正常的字元或空格

8. Estimated life expectancy less than 3 months. 9. Pregnancy (absence confirmed by serum/urine beta human choriongonadotrophin { -HCG}test) or breast-feeding

正確填寫的方式

- 常發生在COPY直接貼取的狀況，所以請檢視有無空格或不正常的字元出現（例如：＜等符號）逐一修正。

四、注意事項

- 若計畫主持人沒有正確填寫臨床試驗計畫資料，電腦系統將拒絕此計畫登錄作業。
- 需於招募第一位受試者參與試驗前完成臨床試驗計劃登錄作業。
- 進行中的臨床試驗計畫，需每6個月更新所登錄的資料內容。

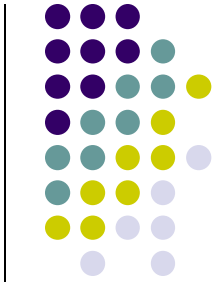
- 已結案之臨床試驗計畫需填寫試驗結果(Result)。
- 請登錄者在使用此系統時，切勿任意變更密碼，因為此組帳號密碼是為全院共同使用的。

ClinicalTrials.gov Protocol Data Element Definitions (DRAFT)

有此符號出現表示必填

March 2010

*	Required by ClinicalTrials.gov
FDAA	Required to comply with US Public Law 110-85, Section 801
(FDAA)	May be required to comply with US Public Law 110-85, Section 801



- **ERROR/WARNING**：messages indicate serious problems that need to be addressed
- **ALERT**：messages indicate problems that need to be addressed
- **NOTE**：messages indicate potential problems that should be reviewed and corrected as needed