試驗登錄clinicaltrials.gov
操作說明

臨床試驗中心 製作

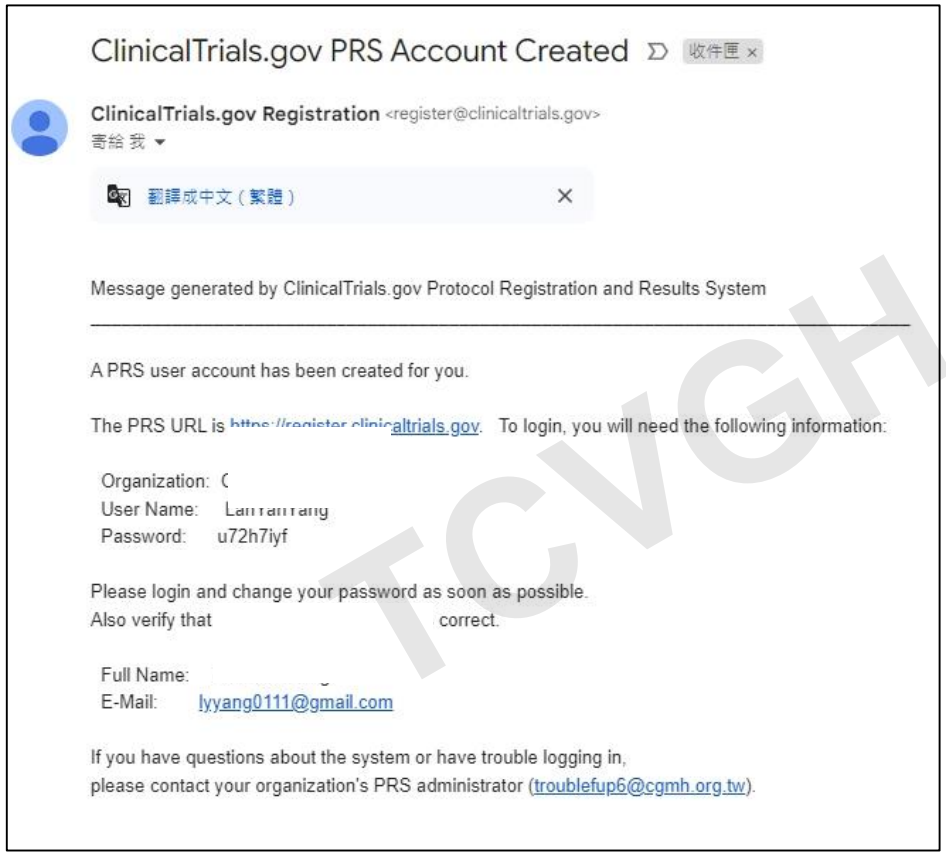
更新日期 113.07.10

帳號申請表

本中心官網申請辦法

Email至 tcvghcrc@vghtc.gov.tw

Email 主旨：【ClinicalTrials.gov帳號申請】



ClinicalTrials.gov PRS Account Created 收件匣 ×

ClinicalTrials.gov Registration <register@clinicaltrials.gov>
寄給 我

翻譯成中文（繁體） ×

Message generated by ClinicalTrials.gov Protocol Registration and Results System

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A PRS user account has been created for you.

The PRS URL is https://register.clinicaltrials.gov. To login, you will need the following information:

Organization: (
User Name: Lanranrang
Password: u72h7iyf

Please login and change your password as soon as possible.
Also verify that correct.

Full Name:
E-Mail: lyyang0111@gmail.com

If you have questions about the system or have trouble logging in,
please contact your organization's PRS administrator (troublefup6@cgmh.org.tw).

帳號申請成功通知信

ClinicalTrials.gov 帳號申請表	
計畫主持人資料	
Investigator Name 完整英文姓名(First Name & Last Name)	
Email Address	
Phone Number	
登錄案件之 IRB 編號	
使用者資料	
User Login Name	
Full User Name	
Other User Information (請填聯絡電話)	
User Email (Login information, including initial password, is sent to this address.)	

首次申請帳號者

對臨床試驗中心提出申請

- Email至：tcvghcrc@vghtc.gov.tw
- Email 主旨：【ClinicalTrials.gov帳號申請】

臨床試驗中心寄出信件(帳號申請表)

- 申請人回覆ClinicalTrials.gov帳號申請表
- 需填寫計畫主持人資料及使用者資料

臨床試驗中心收到PI資料後開立帳號權限

- 申請人收到ClinicalTrials.gov網站提供的Organization、Username、Password的信件後，至ClinicalTrials.gov網站登錄試驗資料

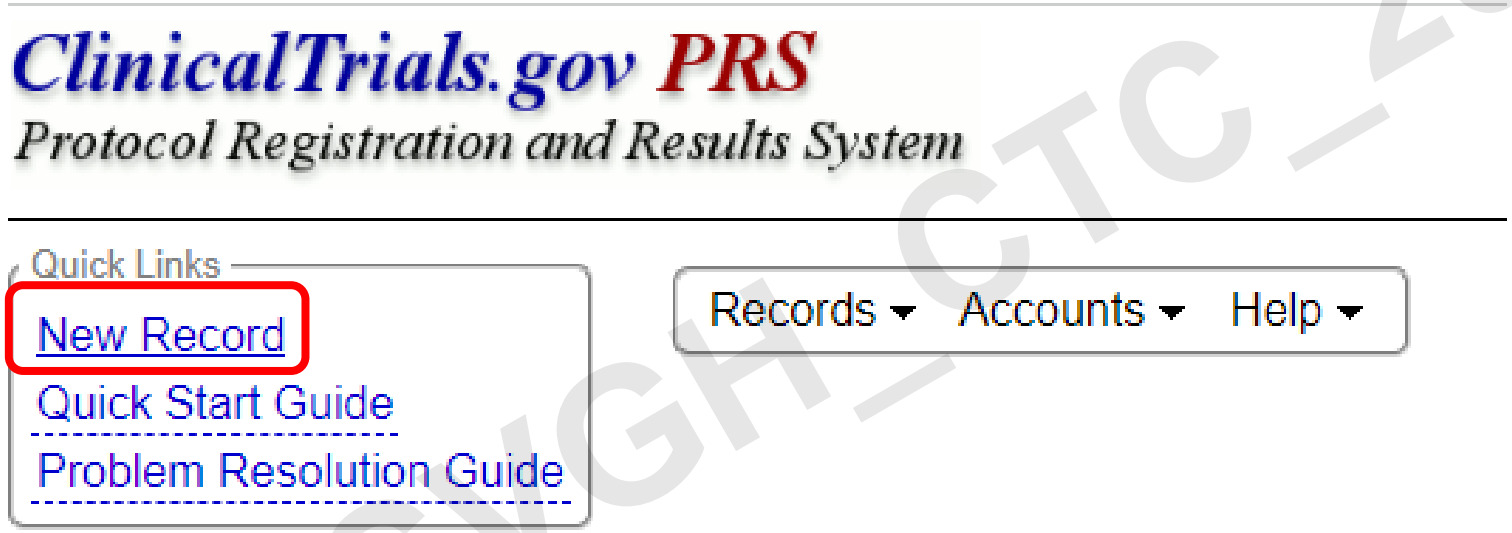
登入

- **Organization:TaichungVGH**
  (本院專用帳號，勿改)

- 需先申請帳號才能登入網站
- 如有登錄上的問題可以撥4780來電詢問喔！

新增新研究案 Create a new record

- 輸入帳密後點選 **New Record**後即可開始編輯



新增新研究案 Create a new record

Help Definitions

* Organization's Unique Protocol ID: 輸入IRB number

* Brief Title: 研究案名稱(不超過3百字)

Special Characters

[*] Acronym: (if any)

If specified, will be included at end of Brief Title in parentheses.

* Study Type:

- Interventional (or clinical trial) — participants assigned to intervention(s) based on a protocol
- Observational participants **not** assigned to intervention(s) based on a protocol; typically in context of routine care
- Expanded Access availability of an experimental drug or device outside of a clinical trial protocol

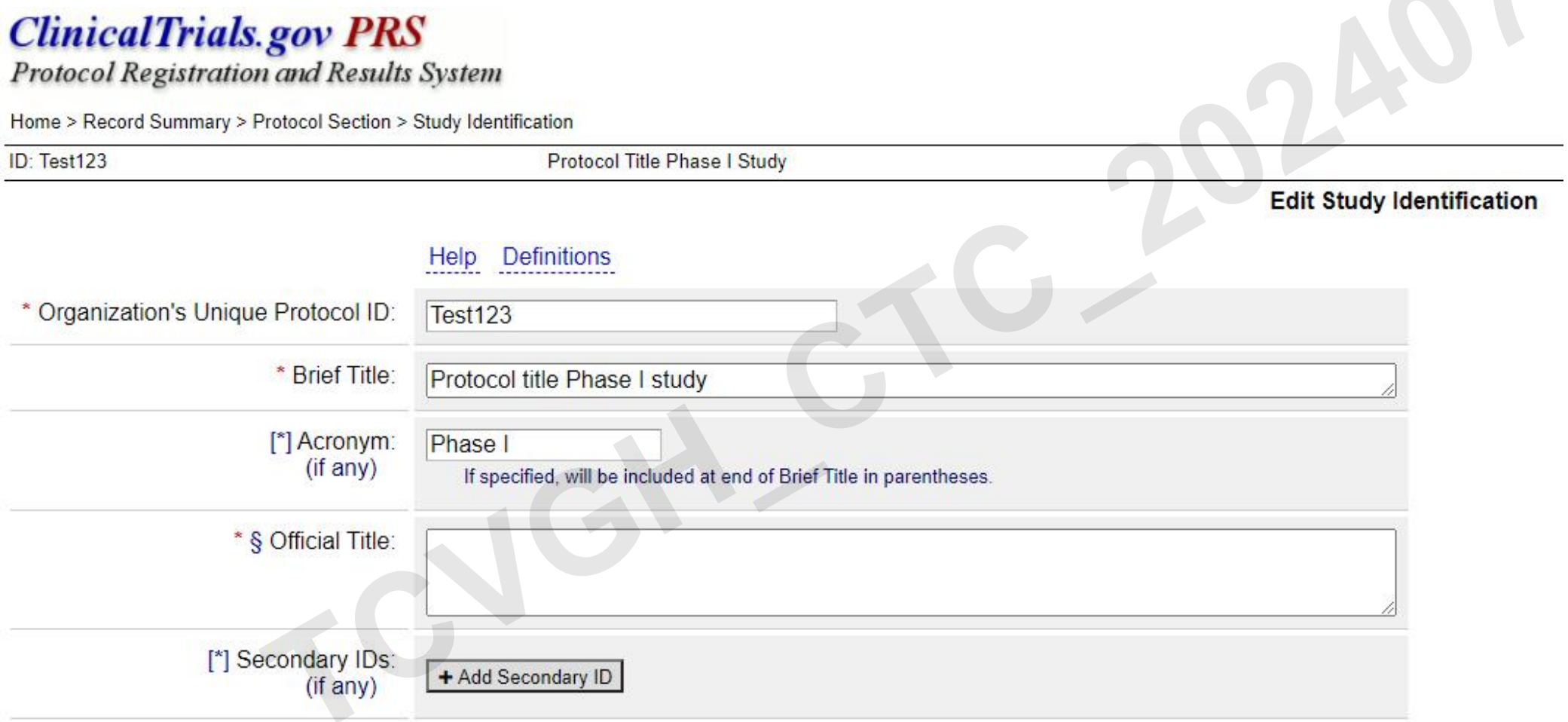
Continue Cancel

* Required

* § Required if Study Start Date is on or after January 18, 2017

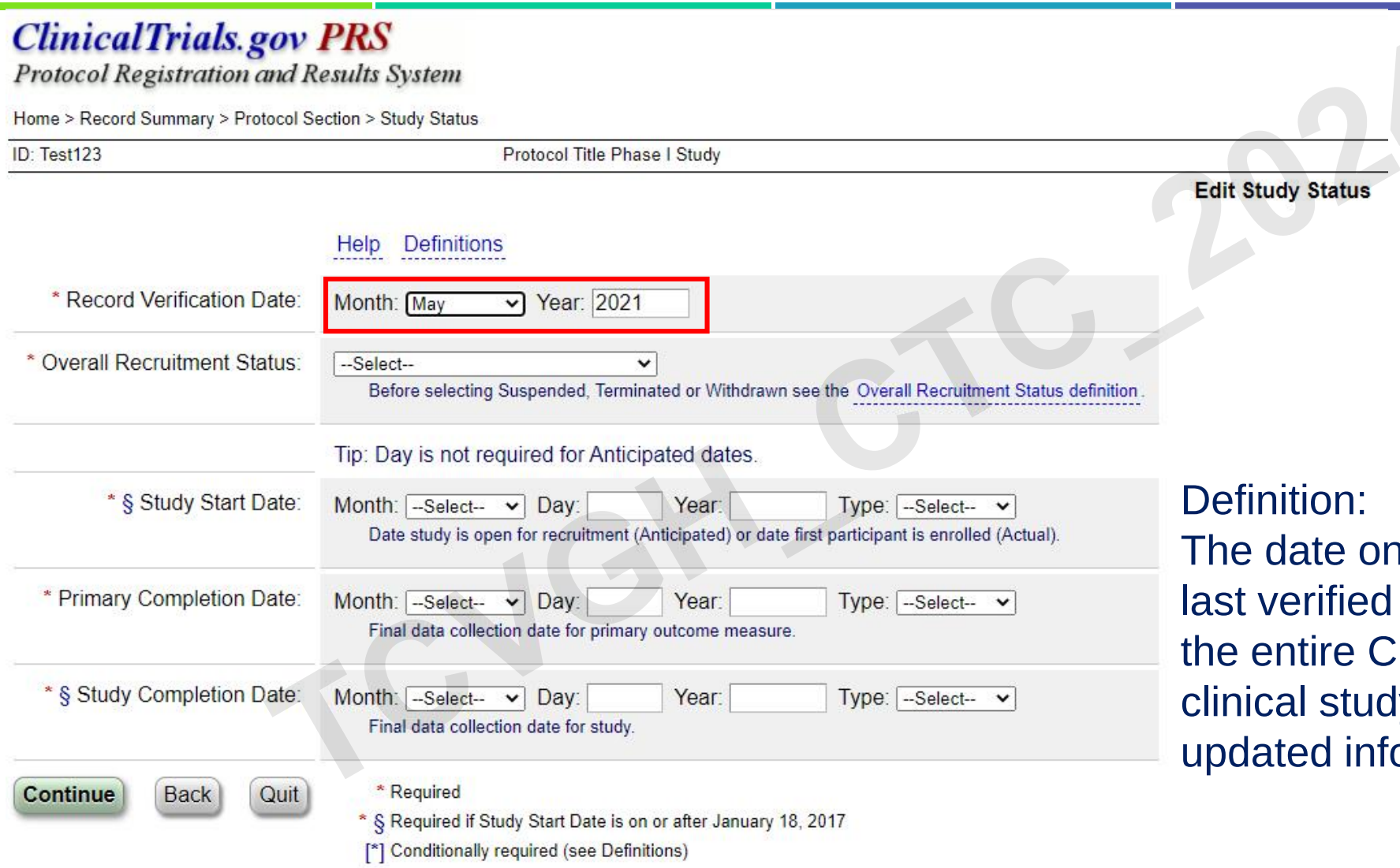
[*] Conditionally required (see Definitions)

新增新研究案 Create a new record



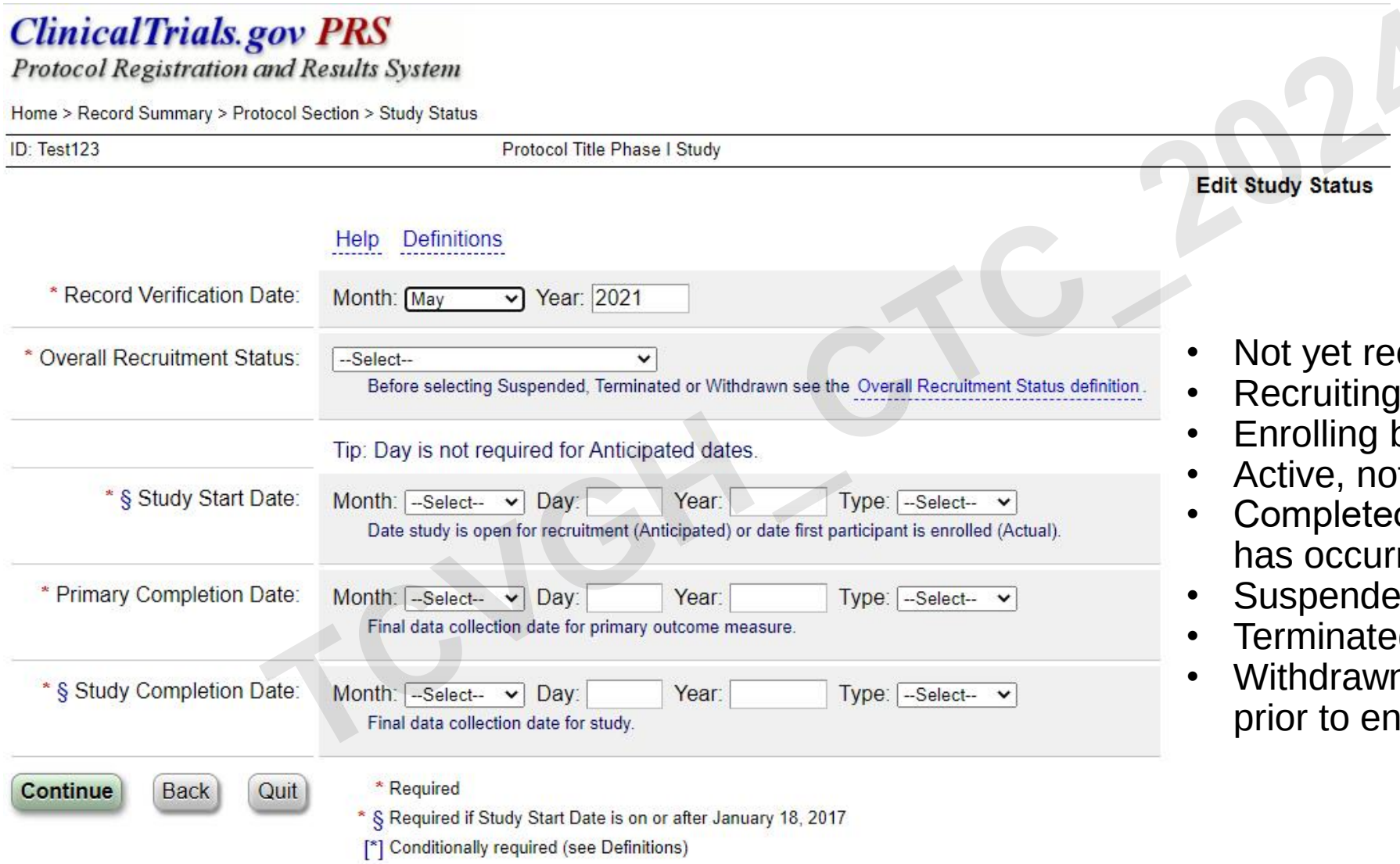
Ex：
Brief Title: Women's Health Initiative
Acronym: WHI（可自行定義）
Displayed on ClinicalTrials.gov as: Women's Health Initiative (WHI)

新增新研究案 Create a new record



Definition:
The date on which the responsible party last verified the clinical study information in the entire ClinicalTrials.gov record for the clinical study, even if no additional or updated information is being submitted.

新增新研究案 Create a new record


ClinicalTrials.gov PRS
Protocol Registration and Results System

Home > Record Summary > Protocol Section > Study Status

ID: Test123 Protocol Title Phase I Study

Edit Study Status

Help Definitions

* Record Verification Date: Month: May Year: 2021

* Overall Recruitment Status: --Select--
Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition.

Tip: Day is not required for Anticipated dates.

* § Study Start Date: Month: --Select-- Day: Year: Type: --Select--
Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual).

* Primary Completion Date: Month: --Select-- Day: Year: Type: --Select--
Final data collection date for primary outcome measure.

* § Study Completion Date: Month: --Select-- Day: Year: Type: --Select--
Final data collection date for study.

Continue Back Quit

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Completed (last participant's last visit has occurred)
- Suspended
- Terminated
- Withdrawn (Study halted prematurely, prior to enrollment of first participant)

新增新研究案 Create a new record

Sponsor/Collaborators

Sponsor/Collaborators

Sponsor: Taichung Veterans General Hospital

Responsible Party: Principal Investigator

Investigator:

Official Title:

Affiliation: Taichung Veterans General Hospital

Collaborators:

IIT研究，此項目需填寫PI本人！！（很重要）
送審後PI才會再次收到確認信件

新增新研究案 Create a new record

Oversight

新增新研究案 Create a new record

Oversight

ClinicalTrials.gov PRS
Protocol Registration and Results System

Home > Record Summary > Protocol Section > Oversight

ID: Test123 Protocol Title Phase I Study

Edit Oversight

Help Definitions

* § U.S. FDA-regulated Drug: --Select--
Studying one or more U.S. FDA-regulated drug or biologic products?
For more information see the "Elaboration" in the Applicable Clinical Trial (ACT) Checklist (PDF).

* § U.S. FDA-regulated Device: --Select--
Studying one or more U.S. FDA-regulated device products?
For more information see the "Elaboration" in the Applicable Clinical Trial (ACT) Checklist (PDF).

* U.S. FDA IND/IDE: --Select--
(Not public)
Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?

* Human Subjects Protection Review:
Board Status: Submitted, approved

The following information is required if the study meets each of these criteria: not required to be registered under 42 CFR Part 11, not func
or IDE. [This information is not made public.]

Approval Number:
Board Name:
Board Affiliation:
Board Contact: Phone: Extension:
Email:
Address:

Data Monitoring Committee: --Select--
FDA Regulated Intervention: --Select--

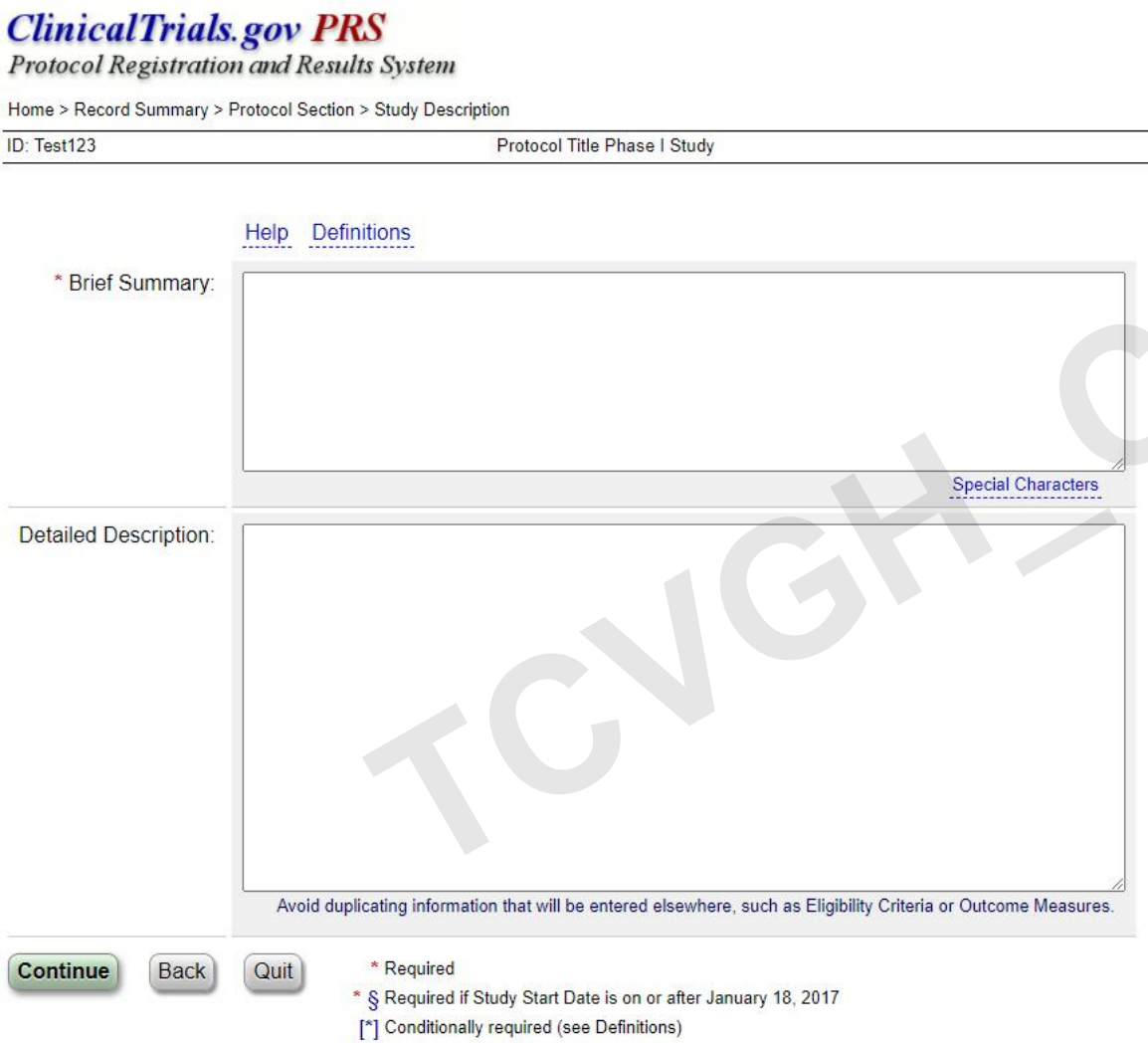
Continue Back Quit

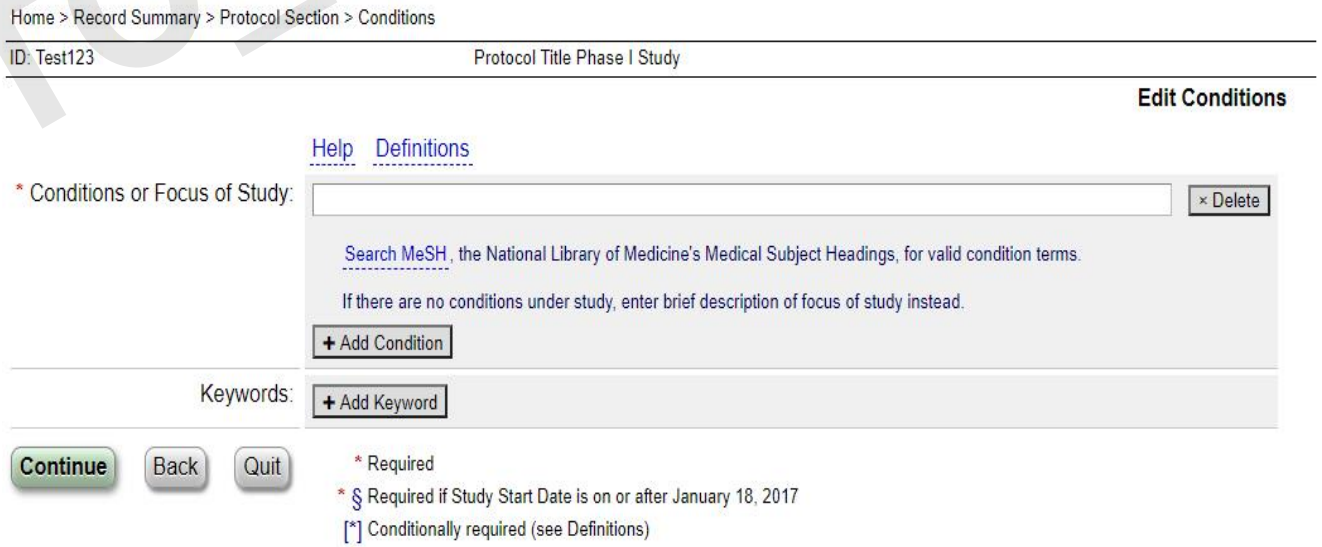
* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Choose ”YES” or “NO” from the drop down.
計畫案來源或經費與美國FDA有關才需填YES

新增新研究案 Create a new record

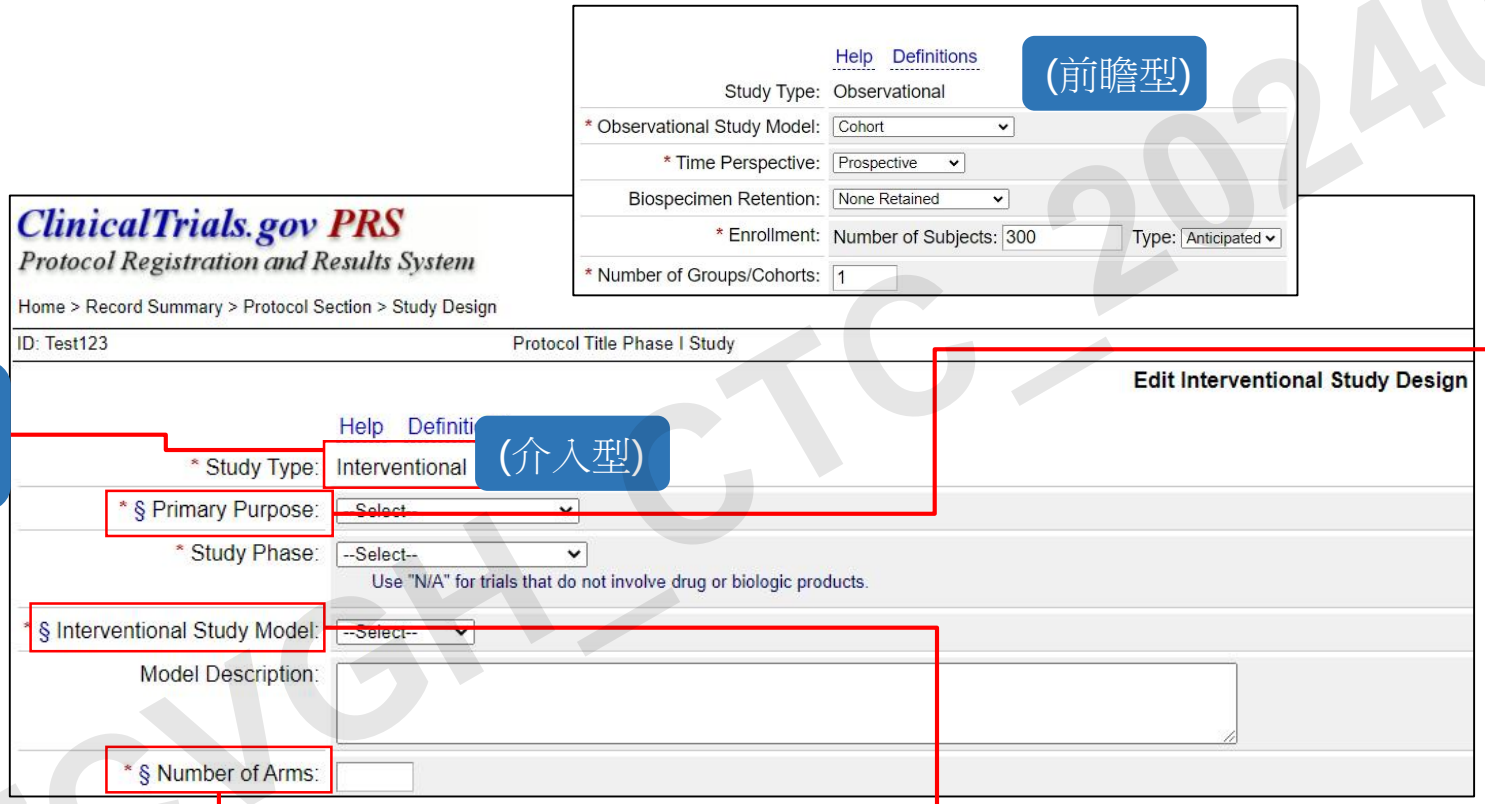
Study description/ Conditions





新增新研究案 Create a new record

Study design



會依前面所選的研究類型自動帶出

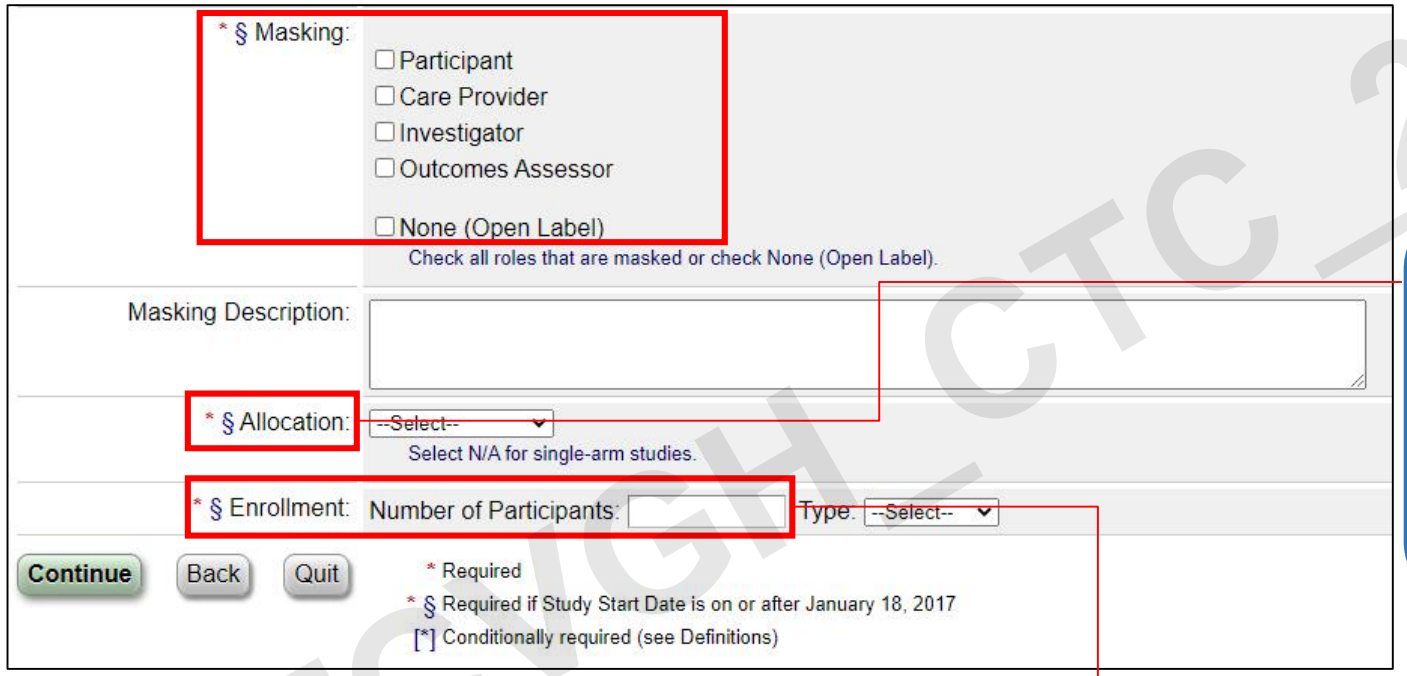
Treatment
Prevention
Diagnostic
Supportive Care
Screening
Health Services Research
Basic Science
Device
Other

Single Group
Parallel
Crossover
Factorial
Sequential

Note: "Arm" means a pre-specified group or subgroup of participant(s) in a clinical trial assigned to receive specific intervention(s) (or no intervention) according to a protocol.

新增新研究案 Create a new record

Study design



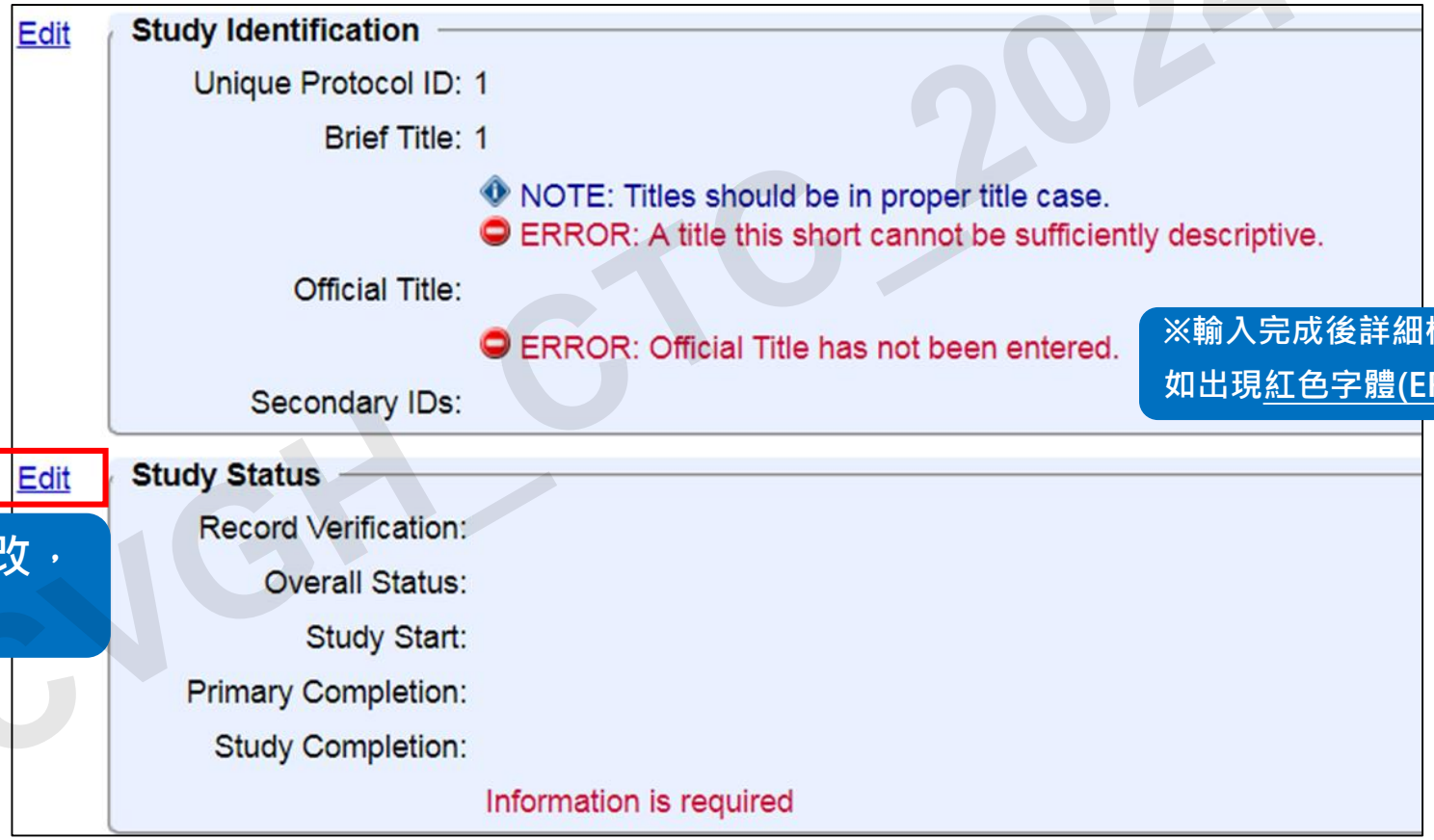
Definition: The method by which participants are assigned to arms in a clinical trial.

- N/A (not applicable)
- Randomized
- Nonrandomized

Definition: The estimated total number of participants to be enrolled (target number) or the actual total number of participants that are enrolled in the clinical study.

新增新研究案 Create a new record

Registration

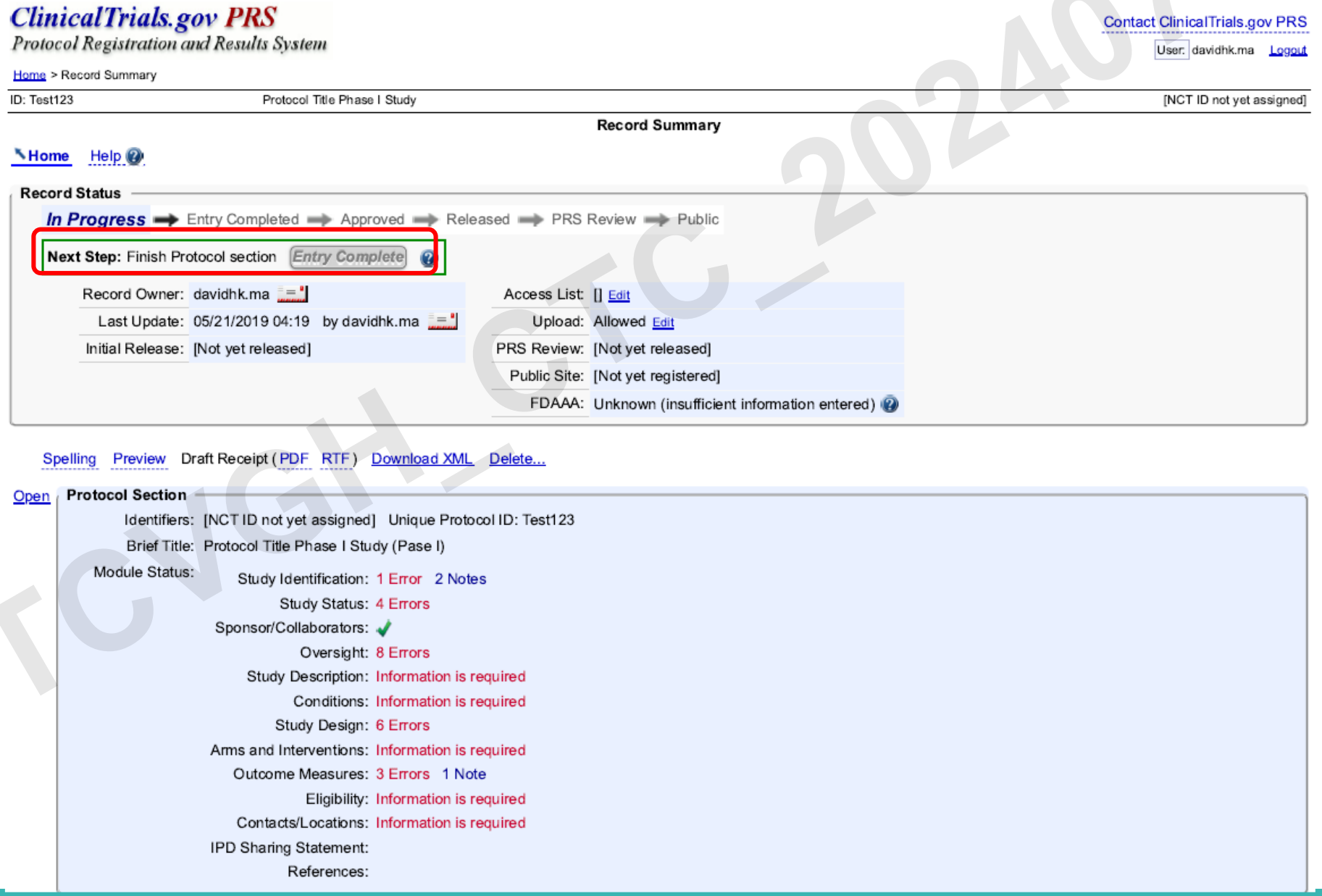


若要繼續編輯或修改，
選擇Edit繼續編輯

※輸入完成後詳細檢視您登錄的資料，
如出現紅色字體(ERROR)為登錄資料不完全

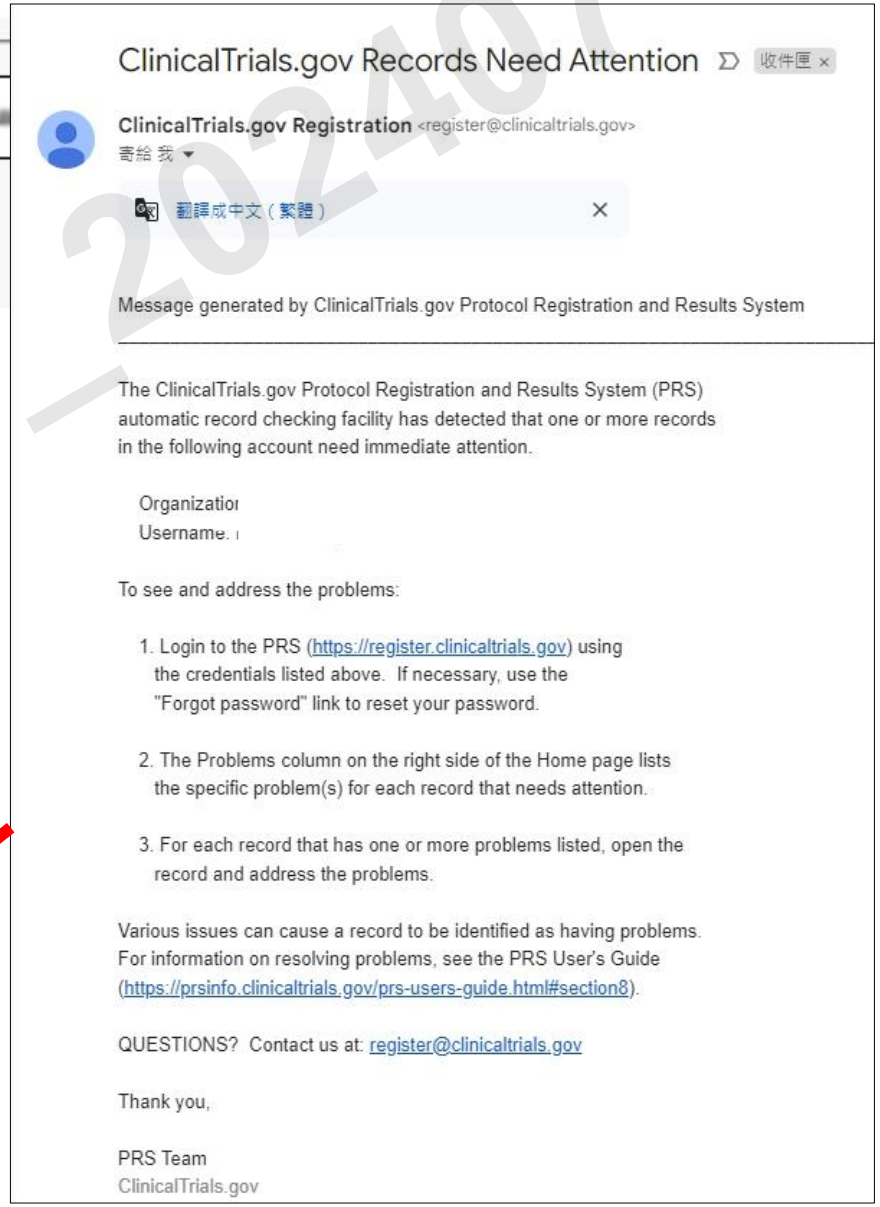
新增新研究案 Create a new record

Registration



新增新研究案 Create a new record

此狀態網站會寄確認信件給PI，需至信件點選”同意”才會開始進入審查階段


ClinicalTrials.gov Records Need Attention

收件匣 ×

ClinicalTrials.gov Registration <register@clinicaltrials.gov>
寄給 我

翻譯成中文（繁體）

Message generated by ClinicalTrials.gov Protocol Registration and Results System

The ClinicalTrials.gov Protocol Registration and Results System (PRS) automatic record checking facility has detected that one or more records in the following account need immediate attention.

Organizatio
Username.

To see and address the problems:

1. Login to the PRS (https://register.clinicaltrials.gov) using the credentials listed above. If necessary, use the "Forgot password" link to reset your password.
2. The Problems column on the right side of the Home page lists the specific problem(s) for each record that needs attention.
3. For each record that has one or more problems listed, open the record and address the problems.

Various issues can cause a record to be identified as having problems. For information on resolving problems, see the PRS User's Guide (https://prsinfo.clinicaltrials.gov/prs-users-guide.html#section8).

QUESTIONS? Contact us at: register@clinicaltrials.gov

Thank you,

PRS Team
ClinicalTrials.gov

PI收到這封信件點選Approved後才會進到下一階段

新增新研究案 Create a new record

Study Result

- Results Section
  1. Participant Flow
  2. Baseline Characteristics
  3. Outcome Measures
  4. Adverse Event Information
  5. Limitations and Caveats
  6. Certain Agreements
  7. Results Point of Contact
  8. Delayed Results (Optional)

Study completion 之後再填
填寫Results Section後無法再修改變更登錄資料

總結

- 若沒有正確填寫試驗計畫資料，系統將拒絕此計畫登錄作業
- 需於招募第一位受試者前完成臨床試驗計劃登錄作業
- 補登容易發生邏輯錯誤以及影響科學性
- 進行中的臨床試驗，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)
- 英文版protocol (draft可)為必備文件