臺大醫院臨床試驗計劃案登錄
Clinical Trial Registration

臨床試驗中心 統計諮詢小組

2025/04

Objectives

* Background for Registration
* Procedures for registering your Clinical Trial
* Frequently Asked Question

Background for Registration

Why Clinical Trial Registration?

* **Required by Law**

  Section 801 of the Food and Drug Administration Amendments Act (FDAAA801) requires Responsible Parties to register and submit summary results of clinical trials with ClinicalTrials.gov. The law applies to certain clinical trials of drugs (including biological products) and medical devices.

* **Required for Journal Publication**

  International Committee of Medical Journal Editors (ICMJE) requires trial registration as a condition for the publication of research results generated by a clinical trial.

Why Clinical Trial Registration?

In 2005, the International Committee of Medical Journal Editors (ICMJE) initiated a policy requiring investigators to deposit information about trial design into an accepted clinical trials registry before the onset of patient enrollment.

2005年國際醫學雜誌編輯委員會之投稿規定

* **經倫委會核准之臨床試驗，需於招募第一位受試者參與前，將臨床試驗計劃資料登錄於臨床試驗公開網站。**
* **未完成臨床試驗登錄之計畫案，ICMJE有權不接受其文章發表。**

Name	Type	Intervention Type	Registration Policy Scope	Results Submission Policy Scope
Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) (PDF)	U.S. Federal law enacted in 2007	Drugs, biologics, and devices	Controlled clinical investigations of an FDA-regulated drug, biologic, or device, other than Phase 1 (drugs/biologics) or small feasibility studies	Same scope as registration, but interventional studies of FDA approved drugs, biologics, or devices
2013 Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects	International policy initially adopted by the World Medical Association (WMA) General Assembly in 1964; last amended in 2013	Any (includes drugs, biologics, devices, surgical procedures, and behavioral treatments)	"Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject." (Para 35)	"Researchers have a duty to make publicly available the results of their research on human subjects... Negative and inconclusive as well as positive results should be published or otherwise made publicly available." (Para 36.)
Clinical Trials Directive (2001/20/EC), Article 11 (and associated Regulations and Guidelines)	European Union directive adopted in 2001	Drugs and biologics	Phase 2–4 adult trials and Phase 1–4 pediatric trials	Same scope as registration (includes products without marketing authorization applications)
WHO International Clinical Trials Registry Platform	International policy initiated in 2006	Any (includes drugs, biologics, devices, surgical procedures, and behavioral treatments)	"The registration of all interventional trials is a scientific, ethical and moral responsibility."	N/A
ICMJE Statement	Publication policy initiated in 2004	Any (includes drugs, biologics, devices, surgical procedures, and behavioral treatments)	All interventional studies, including Phase 1 studies; defines criteria for "acceptable registries"	N/A
Section 113 of the Food and Drug Administration Modernization Act	U.S. Federal law enacted in 1997	Drugs and biologics	Efficacy trials for "serious or life threatening diseases or conditions" regulated by FDA	N/A

Why Clinical Trial Registration?

Registry Purpose	Group That Benefits
Fulfill ethical obligations to participants and community	Patients, general public, research community
Provide information to potential participants and referring clinicians	Patients, clinicians
Reduce publication bias	Users of the medical literature
Help editors and others understand the context of study results	Journal editors, users of the medical literature
Promote more efficient allocation of research funds	Granting agencies, research community
Help institutional review boards (IRBs) determine appropriateness of a research study	IRBs, ethicists

Source: Zarin DA, Keselman A. Registering a clinical trial in ClinicalTrials.gov. *Chest*. 2007;131(3):909-12. [Full Text]

What is a Clinical Trial?

World Health Organization Definition

* A clinical trial is ' *Any research project that prospectively assigns human participants or groups to one or more health-related interventions to evaluate the effects on health outcomes.*‘

Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.

對任何受試者進行與健康有關的介入措施以評估對健康影響的計畫。

What is a Clinical Trial?

International Committee of Medical Journal Editors, ICMJE Definition(2007)

* **WHO's Definition:** A clinical trial is "Any research study that prospectively assigns human participants or groups of humans to one or more health related interventions to evaluate the effects on health outcomes."

Health-related interventions *include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes).*

Health outcomes *include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.*
藥物動力學、不良事件反應

What is a Clinical Trial?

ClinicalTrials.gov Definition

A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials and observational studies. ClinicalTrials.gov includes both interventional and observational studies.

* **Interventional:** studies in human beings in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed.

* **Observational:** studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study.

What is a Clinical Trial?

醫療法第八條:

* 本法所稱人體試驗，係指醫療機構依醫學理論於人體施行新醫療技術、新藥品、新醫療器材及學名藥生體可用率、生體相等性之試驗研究。

Who is Responsible for Registering?

* 由研究者自行發起之研究案且責任歸屬於Principal investigator(PI)，應由計畫主持人於取得倫委會同意函後完成登錄。

* 有廠商贊助(Sponsor)之計畫，贊助者應主動完成登錄。

When is Timing for Registration?

* 21 days after 1st patient is enrolled (PL 110-85)
* Prior to enrollment of 1st patient (ICMJE)

Web Site Registry

* 臺大醫院已向美國國家衛生研究院(National Institutes of Health, NIH) clinicaltrials.gov網站申請本院專用帳號。

* 供本院研究者自行發起研究案之計畫主持人(PI)登錄其臨床試驗研究計劃。

* 帳號密碼請院內網查詢。

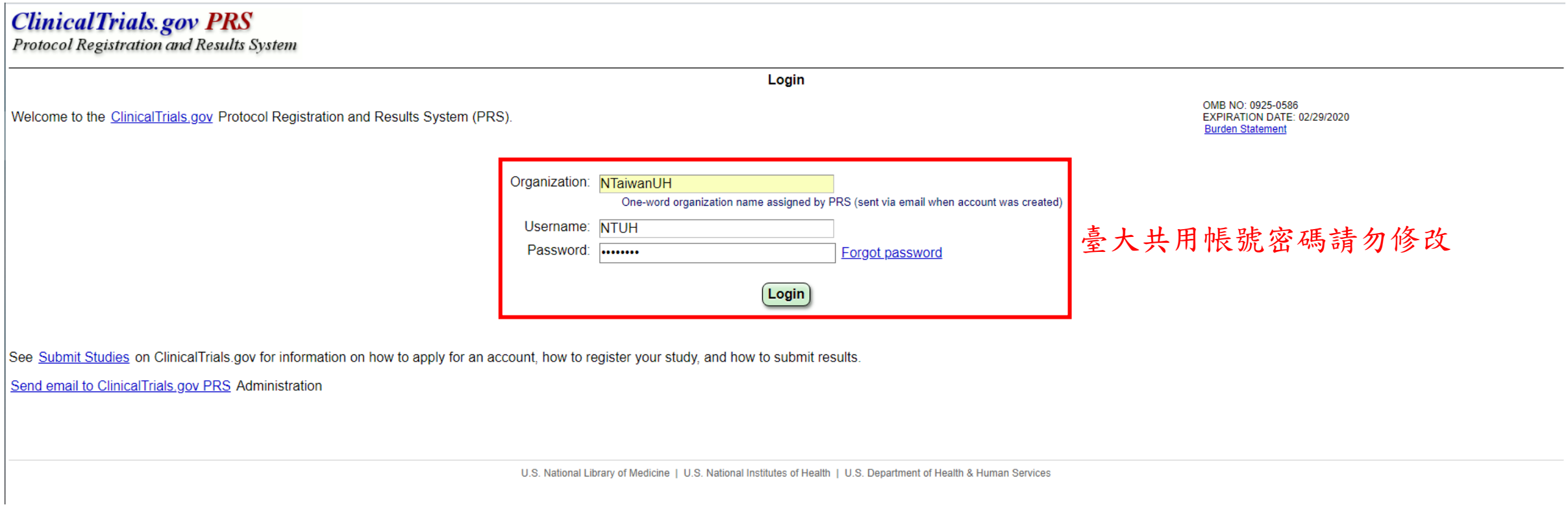
Procedures for registering your Clinical Trial

How to Register?

ClinicalTrials.gov Protocol Registration System (PRS)

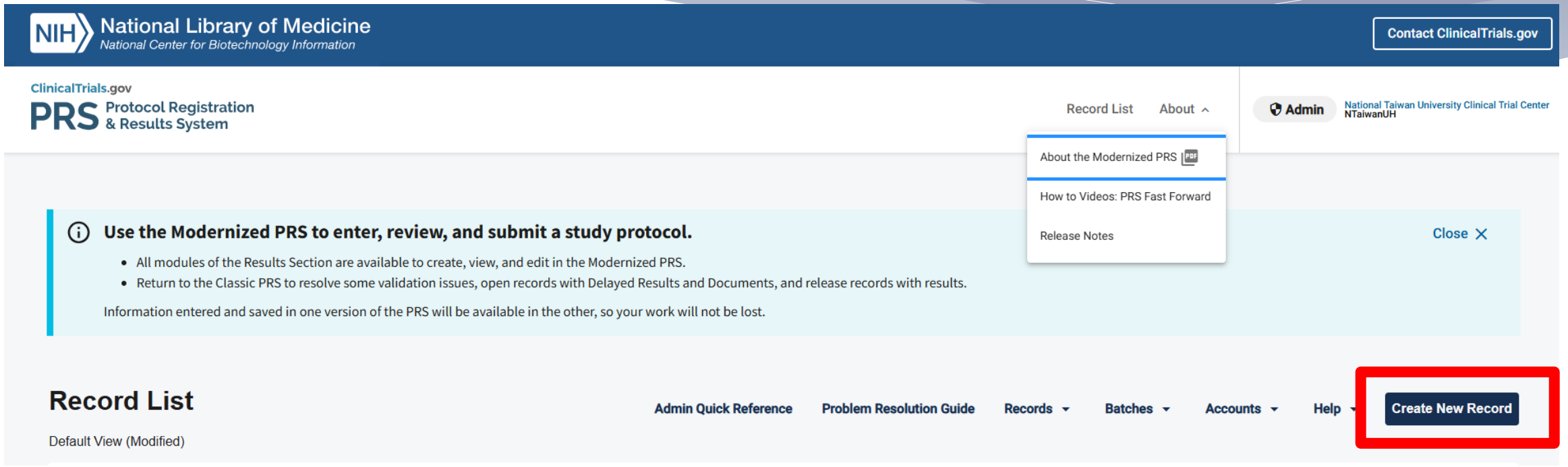
http://register.clinicaltrials.gov

ClinicalTrials.gov Protocol Registration System Login

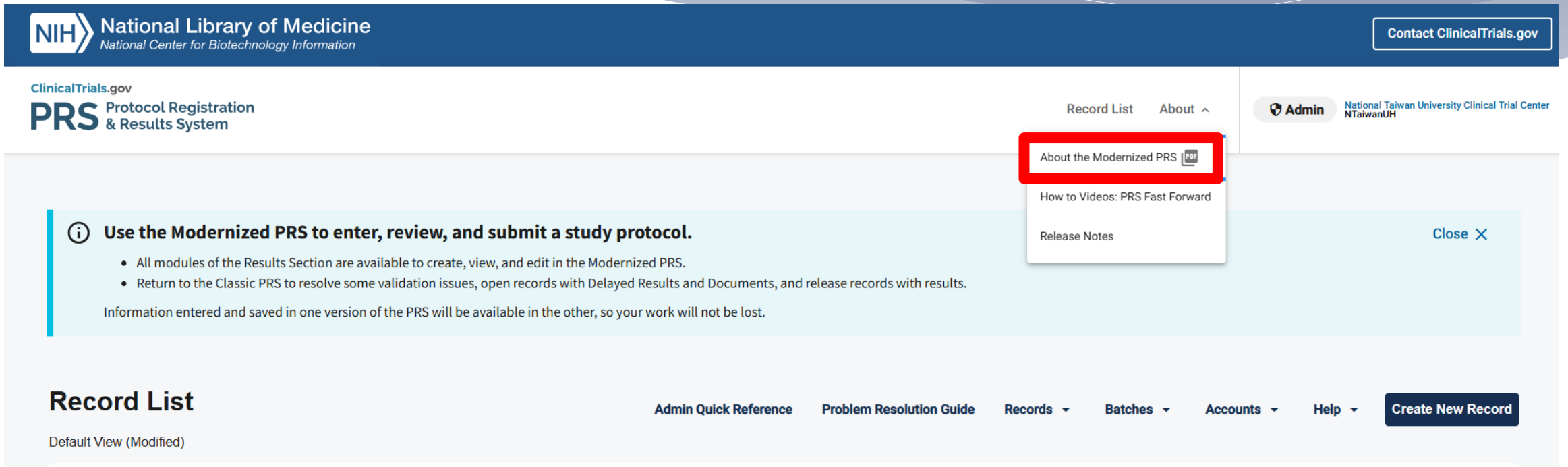


臺大共用帳號密碼請勿修改

Register for your Clinical Trial



User's Guide


National Library of Medicine
National Center for Biotechnology Information
Contact ClinicalTrials.gov
ClinicalTrials.gov
PRS Protocol Registration & Results System
Record List
About
Admin
National Taiwan University Clinical Trial Center
NTaiwanUH
About the Modernized PRS
How to Videos: PRS Fast Forward
Release Notes
Use the Modernized PRS to enter, review, and submit a study protocol.
All modules of the Results Section are available to create, view, and edit in the Modernized PRS.
Return to the Classic PRS to resolve some validation issues, open records with Delayed Results and Documents, and release records with results.
Information entered and saved in one version of the PRS will be available in the other, so your work will not be lost.
Close
Record List
Default View (Modified)
Admin Quick Reference
Problem Resolution Guide
Records
Batches
Accounts
Help
Create New Record

Required Item

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

[*] Conditionally required (see Definitions)

Organization's Unique Protocol ID *

Enter your IRB approve number

Brief Title *

Write a short, easy-to-understand version of the official study title using title case.

Protocol Title (Limit: 300 characters)

300 characters allowed , at least 18 characters required

Acronym [*]

Required if one exists. It will be included in parentheses at the end of the Brief Title.

14 characters allowed

Study Type *

- ◯ Interventional

  Participants are assigned to one or more interventions, based on a protocol.

- ◯ Observational

  Participants are **not** assigned to interventions based on a protocol.

- ◯ Expanded Access

  Participants receive an experimental drug or device outside of a clinical trial protocol.

Official Title * §

Provide the title used in the study protocol. Use title case.

600 characters allowed

Official Title (Limit: 600 characters)

Secondary IDs [*] 

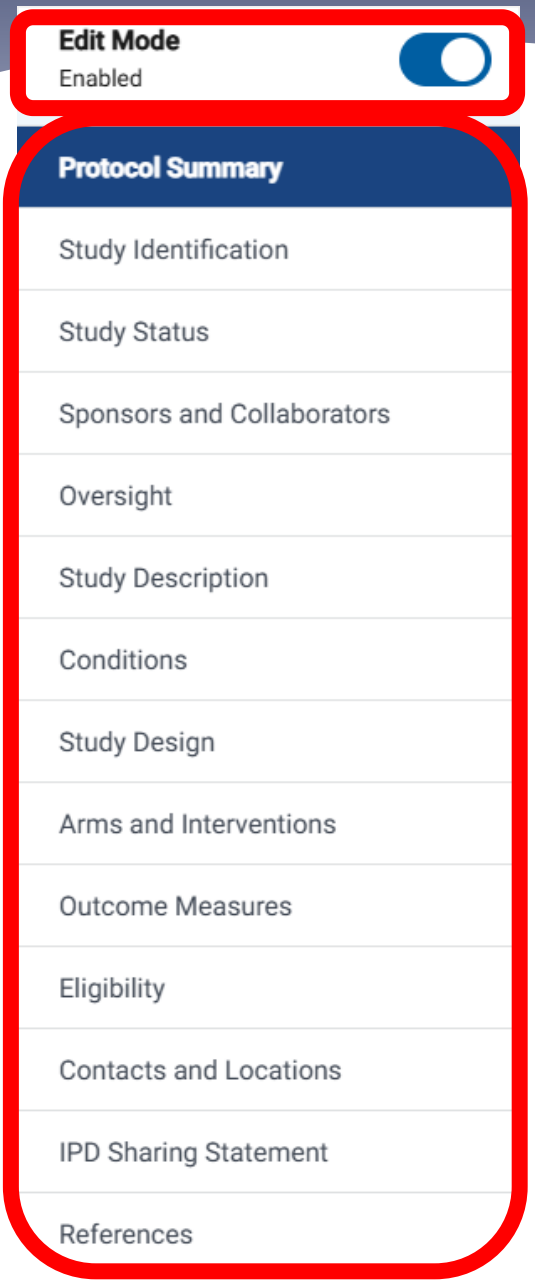
These should be provided if they exist. If the study is funded by a U.S. Federal Government agency, the grant or contract number must be included as a Secondary ID.

Secondary ID Type

Create Record

Cancel record creation

Required Information



編輯前請確認編輯模式是否開啟

請依序按照計畫書內容填寫

Brief Title * 

Write a short, easy-to-understand version of the official study title using title case.

aaaaaaaaaaaaaaaaaaaaaaaaa

274 characters left

Acronym [*] 

Required if one exists. It will be included in parentheses at the end of the Brief Title.

14 characters allowed

Official Title * § 

Provide the title used in the study protocol. Use title case.

Error: A title this short cannot be sufficiently descriptive.

aaaaaaa

593 characters left

Example:

- **Brief Title:** Women's Health Initiative
- **Acronym:** WHI
- **Displayed on ClinicalTrials.gov as:**

  Women's Health Initiative (WHI)

ID: Enter Your IRB Approve Number | Protocol Title | [NCT ID not yet assigned]

Edit Study Status

Help Definitions

* Record Verification Date:	Month: August Year: 2018
* Overall Recruitment Status:	--Select-- Before selecting Suspended, Terminated or Withdrawn see the Overall Recr
	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 enr
* 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)

Definition:

Date the protocol information was last verified. Verification date is shown along with organization name on ClinicalTrials.gov to indicate to the public whether the information is being kept current, particularly recruiting status and contact information.

Update verification date when reviewing the record for accuracy and completeness, even if no other changes are made.

Record Verification Date *

Month *

Apr

Year *

2025

Definition:

Date the protocol information was last verified. Verification date is shown along with organization name on ClinicalTrials.gov to indicate to the public whether the information is being kept current, particularly recruiting status and contact information.

Update verification date when reviewing the record for accuracy and completeness, even if no other changes are made.

Overall Recruitment Status *

If you select "Suspended," "Terminated," or "Withdrawn," an explanation of why the study was stopped is required.

Error: Overall Recruitment Status is a required field.

- Select -

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Completed
- Suspended
- Terminated
- Withdrawn

Study Start Date * §

Date of enrollment of the first participant.
The Day field is optional for anticipated dates.

Error: Study Start Date has not been entered.

Month **Day** **Year**

Type

- ◯ Anticipated
- ◯ Actual

Date that enrollment to the protocol begins

Primary Completion Date *

Final data collection date for the primary outcome measures.
The Day field is optional for anticipated dates.

Error: Primary Completion Date has not been entered.

Month **Day** **Year**

Type

- ◯ Anticipated
- ◯ Actual

- Date the final Subject was examined or received an intervention for the purposes of final collection of data for the primary outcome.
- Choose from: Anticipated and Actual.

Study Completion Date * §

Final data collection date for the primary outcome measures, secondary outcome measures, and adverse event information.
The Day field is optional for anticipated dates.

Error: Study Completion Date has not been entered.

Month **Day** **Year**

Type

- ◯ Anticipated
- ◯ Actual

- Final date on which study data was (or is expected to be) collected.
- Choose from: Anticipated and Actual

Responsible Party, by Official Title *

Select the type of responsible party - usually the sponsor.

- (•) Sponsor
- ( ) Principal Investigator
- ( ) Sponsor-Investigator

Select Sponsor

Name of the Sponsor *

National Taiwan University Hospital

Enter "National Taiwan University Hospital"

Collaborators

Enter the **name of an organization** providing support for the study.

Add Collaborator

請輸入合作對象(其他醫院/廠商等)英文全名

160 characters allowed

U.S. FDA-Regulated Product

U.S. FDA-regulated Drug * §

Is the study investigating one or more U.S. FDA-regulated drug or biologic products?

Error: U.S. FDA Regulated Drug has not been entered.

- ◯ Yes
- ◯ No

Indication that a clinical study is studying a drug product (including a biological product) subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of the Public Health Service Act. Select Yes/No.

U.S. FDA-regulated Device * §

Is the study investigating one or more U.S. FDA-regulated device products?

Error: U.S. FDA Regulated Device has not been entered.

- ◯ Yes
- ◯ No

Indication that a clinical study is studying a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act. Select Yes/No.

Investigational New Drug Application (IND)/Investigational Device Exemption (IDE) Information

U.S. FDA IND/IDE *

Is this study being done under a U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?

Error: U.S. FDA IND/IDE Study has not been entered.

- ◯ Yes
- ◯ No

IND/IDE Protocol? *(FDAAA)

Definition: Indicate if the protocol involves an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) under US Food and Drug Administration regulations

若您的計畫案預計向美國FDA申請新藥或新醫療技術登記，才需填YES。

Board Status *

The information below must be provided if the study is **not**:

- Required to be registered under 42 CFR Part 11
- Funded by the U.S. government
- Conducted under an IND or IDE.

This information will not be displayed on ClinicalTrials.gov.

Error: Review Board Status is a required field.

Submitted, approved

Approval Number [*]

Board Name [*]

Board Affiliation [*]

255 characters allowed

請按照下方文字輸入

- **Board Name:**
  National Taiwan University Hospital
  Research Ethics Committee
- **Board Affiliation:**
  National Taiwan University Hospital

Board Contact Information [*]

Phone

Ext.

Email

Address

請按照下方文字輸入

- Phone:
  +886-2312-3456 Extension: 88576
- Email:
  fctsai@ntu.edu.tw
- Address:
  No.1, Changde St., Zhongzheng Dist., Taipei City 100,Taiwan

Data Monitoring Committee

Data Monitoring Committee

- ◯ Yes
- ◯ No

Choose "YES" or "NO" from the drop down.
If the study has a Medical Monitor but no DMC, the answer is "NO".

Brief Summary *

Use these resources to provide understandable information about this study to patients, families, and health care providers:
Plain language checklist for Brief Summary
Template for Brief Summary

Error: Brief Summary is a required field.

5,000 characters allowed

Primary disease or condition being studied, or focus of the study

Detailed Description

Avoid duplicating information that will be entered or uploaded elsewhere in the record.

32,000 characters allowed

Definition:
Extended description of the protocol, including more technical information (as compared to the Brief Summary) if desired. Don not include the entire protocol; do not duplicate information recorded in other data elements, such as eligibility criteria or outcome measures. (Limit: 32,000 characters)

Conditions or Focus of Study *

Enter each disease or condition being studied.
If no disease or condition is being studied, enter a brief description of the focus of the study.

Error: Specify at least one condition or the focus of the study.

Add Condition

Primary disease or condition being studied, or focus of the study

Keywords

Enter words or phrases that precisely describe the study protocol to help users find this study on ClinicalTrials.gov.

Add Keyword

Words or phrases the best describe the protocol. Avoid acronyms and abbreviations.

Primary Purpose * §

Select the option that best describes the aim or goal of the study intervention(s).

Error: Primary purpose has not been entered.

- Select -

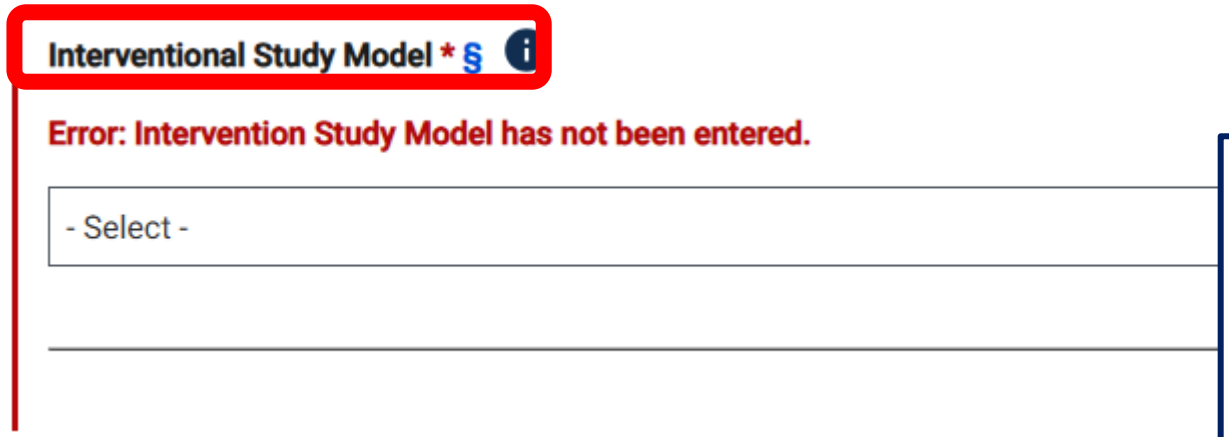
- Treatment
- Prevention
- Diagnostic
- Supportive Care
- Screening
- Health Services Research
- Basic Science
- Device Feasibility
- Other

Study Phase *

Select one. Use "N/A" for trials that do **not** involve drug or biologic products.

Error: Phase is a required field.

Choices are N/A (for trials without Phases), 0, 1, ½, 2, 2/3, 3, and 4.



- **Single Group:**
  single arm study
- **Parallel:**
  participants are assigned to one of two or more groups in parallel for the duration of the study
- **Cross-over:**
  participants receive one of alternative interventions during the initial phase of the study and receive the other intervention during the second phase of the study
- **Factorial:**
  two or more interventions, each alone and in combination, are evaluated in parallel against a control group

Number of Arms * §

Enter the total number of arms participants might be assigned to over the course of the clinical study.

Error: Number of Arms must be at least 1.

Error: Number of Arms has not been entered.

- **Number of interventional groups. Enter 1 for single-arm study.**

Masking * §

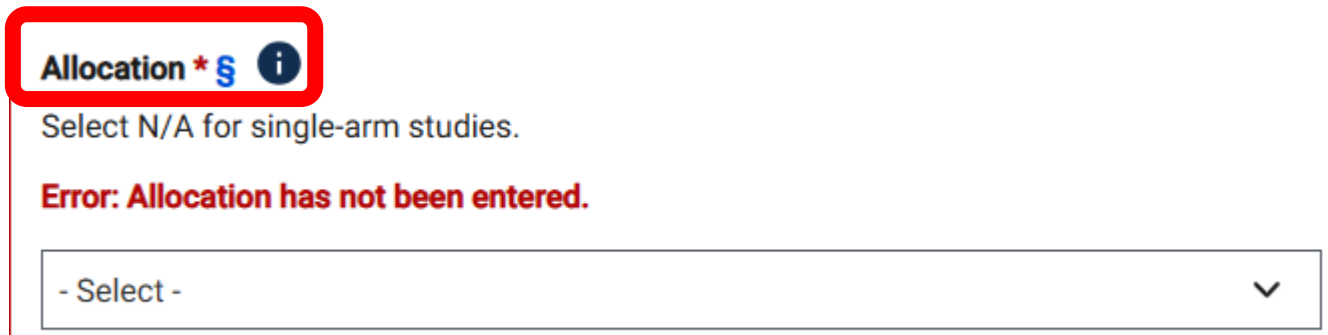
Select all roles that are masked, or select "None (Open Label)."

Error: Masking has not been entered.

- [ ] Participant
- [ ] Care Provider
- [ ] Investigator
- [ ] Outcomes Assessor
- [ ] None (Open Label)

- Single Blind
- Double Blind

- Open



Choices are N/A (for single-arm study), Randomized Controlled Trial or Nonrandomized Trial.

Enrollment * §

Number of Participants

Error: Enrollment needs to be a whole number.

Error: Enrollment has not been entered.

Type

- ◯ Anticipated
- ◯ Actual

Target or Actual Number of Subjects, you specify by selecting Anticipated or Actual in the accompanying Type menu. Upon study completion, you must update this to reflect actual and final total enrollment.

Arms * ⓘ

+ Add Arm

Interventions * ⓘ

+ Add Intervention

Arm Title *

Enter a brief, descriptive title for this arm of the study.

100 characters allowed

The short name used to identify the arm. (Limit: 100 characters)

Arm Type *

- Select -

6 item Pick list :

- Experimental
- Active Comparator
- Placebo Comparator
- Sham Comparator
- No intervention
- Other

Arm Description [*]

Use this field to provide additional information about the arm, including a description of the intervention(s) administered

999 characters allowed

May not be needed, if the Arm Label says all that's needed. If you use it. Limit is 999 characters.

+ Add Arm

Remove

Arms * ⓘ

⊕ Add Arm

Interventions * ⓘ

⊕ Add Intervention

Intervention Type * ⓘ

Select the type of intervention.

- Select -

Intervention Name * ⓘ

Enter a brief, descriptive name for the intervention. Use a non-proprietary (generic) name if available.

200 characters allowed

Other Intervention Names (if any) [*] ⓘ

Enter one name at a time. Include any alternative names or numbers used to identify the intervention.

Add Other Name

200 characters allowed

Intervention Description * § ⓘ

Add details that will distinguish this intervention from other interventions in this or another clinical study.

1,000 characters allowed

Intervention Type * FDAAA - select one per intervention

- Drug (including placebo)
- Device (including sham)
- Biological/Vaccine
- Procedure/Surgery
- Radiation
- Behavioral (e.g., Psychotherapy, Lifestyle Counseling)
- Genetic (including gene transfer, stem cell and recombinant DNA)
- Dietary Supplement (e.g., vitamins, minerals)
- Combination Product
- Diagnostic Test
- Other

Intervention Type *

Select the type of intervention.

- Select -

Intervention Name *

Enter a brief, descriptive name for the intervention. Use a non-proprietary (generic) name, if available.

200 characters allowed

Other Intervention Names (if any) [*]

Enter one name at a time. Include any alternative names or numbers used to identify the intervention.

Add Other Name

200 characters allowed

Intervention Description * §

Add details that will distinguish this intervention from other interventions in this or another clinical study.

1,000 characters allowed

For drugs use generic name; for other types of interventions provide a brief descriptive name. (Limit: 200 characters)

(Limit: 1000 characters)
Example:
50 mg/m2, IV (in the vein) on day 5 of each 28 day cycle.
Number of Cycles: until progression or unacceptable toxicity develops.

Outcome Measure Type

- (●) Primary Outcome Measure
- ( ) Secondary Outcome Measure
- ( ) Other Pre-Specified Outcome

Primary Outcome Measure * ⓘ

Title * ⓘ

254 characters allowed

A concise name for the specific measure that will be used to determine the effect of the intervention(s) or, for observational studies ,
Limit: 254 characters

Description [*] ⓘ

999 characters allowed

Time Frame * ⓘ

254 characters allowed

Time point(s) at which outcome measure is assessed.
(Limit: 254 characters)

Examples of Outcome Measure Titles and Time Frames

Safety/Adverse Event Outcome Measure

Title: Number of Participants with Serious and Non-Serious Adverse Events
Time Frame: Up to 3 weeks

[Source: TTT Workshop – Dose Escalation Study Design (modified)]

Time-to-Event Outcome Measure

Title: Time to Disease Progression
Time Frame: up to 31 months

[Source: Helpful Hints – Parallel Design Example (modified)]

Efficacy Outcome Measure

Title: Percentage of Participants with ≥ 50% Decrease in Pain Visual Analogue Scale (VAS)
Time Frame: 8 hours

Pharmacokinetic Outcome Measure

Title: Area Under the Concentration-Time Curve (AUC 0-72h)
Time Frame: prior to the initial dose on day 1 and 0.25, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 7, 8, 16, 24, 36, 48 and 72 hours post-dose

[Source: TTT Workshop – Dose Escalation Study Design]

Change Outcome Measure

Title: Change from baseline in pain on the 11-point Short Pain Scale (SPS-11) at week 24
Time Frame: Baseline, Week 24

[Source: TTT Workshop - Example Parallel Study Design]

Sex *

Select the biological sex of people eligible to participate in the study.

Error: Sex is a required field.

Female

Choices are Male, Female, Both

Gender Based [*]

Is a person's eligibility to participate in the study according to their biological sex limited by their gender identity?.

- ○ Yes
- ◉ No

Yes: Eligibility is based on gender
No: Eligibility is not based on gender
If "Yes", provide descriptive information about Gender criteria.
Limit: 1000 characters.

Age Limits *

Specify the age range of people who are eligible to participate in the study.

Minimum Age *

- (●) No Limit (NA)
- ( ) Minimum Age Limit

Maximum Age *

- (●) No Limit (NA)
- ( ) Maximum Age Limit

Blank with selection of N/A (No Limit) is allowed for minimum, maximum or both.

Eligibility Criteria *

Error: Eligibility Criteria is a required field.

Inclusion Criteria:
-

Exclusion Criteria:
-

19,950 characters left

List criteria with Hyphen, then space, then text in words, phrases or sentences. Limit 15,000 characters.

Central Contact Person *

Enter the main contact person for the study. If there isn't one, enter a contact for each individual facility in the Locations section.

Add Central Contact Person

Central Contact Backup

Enter a person to contact if the central contact isn't available.

Add Central Contact Backup

- 煩請填寫正確聯絡資訊 以利聯繫
- 若未填將直接退件

Overall Study Official

Identify the people who provide scientific leadership for the study.

Add Study Official

Plan to Share IPD

Do you plan to share IPD with other researchers? If you select Yes, you will be asked to describe the plan.

- (●) Yes
- ( ) No
- ( ) Undecided

Plan Description

Describe which specific IPD will be shared.

1,000 characters allowed

Indicate whether there is a plan to make individual participant data (IPD) collected in this study, including data dictionaries, available to other researchers (typically after the end of the study)

Citations

Provide a citation by entering the PubMed ID (PMID) or PubMed Central ID (PMCID) or by typing the full citation in the space provided.

Add Citation

Citations to publications related to the protocol: background and/or results. Provide either the PubMed Unique Identifier (PMID) of an article or enter the full bibliographic citation.

Links

Enter links to websites that provide information that is directly related to the study protocol.

Add Link

Available IPD and Supporting Information

Add Available IPD/Information

確認沒有任何錯誤訊息(WARNING/ERROR messages)產生，最後記得點選”Entry Complete”，方算完成臨床試驗登錄。
若有errors本中心無法送件

Record Information

Record Dates

Last Updated	Initial Release
04/08/2025 10:48	Not yet released

Status Details and Record Owner

PRS Review	Public Site	Record Owner	FDAAA
Not yet released	Not yet registered	Statistical Center, NTUHCTC (NTUH)	Non-ACT (No FDA-regulated drug/device)

Record Status

In Progress — Entry Completed — Approved — Released — PRS Review — Public

Reset to In-Progress

Next step: Approve [Approve]

確認沒有任何錯誤訊息(WARNING/ERROR messages)產生，最後記得點選"Entry Complete"，方算完成臨床試驗登錄。

若有errors本中心無法送件

Description
User is creating (or modifying) the record.
User has finished - record is ready for review.
Administrator (or Responsible Party) has reviewed record and has made any necessary changes.
Administrator (or Responsible Party) has submitted the record to ClinicalTrials.gov.

If you need to edit your protocol

Record List

Admin Quick Reference | Problem Resolution Guide | Records | Batches | Accounts | Help | Create New Record

Default View (Modified)

Enter your Protocol ID or Brief Title

Lookup By | Customize Columns | Saved Views | Export

Search All Columns

View Record	Group	Unique Protocol ID	Tags	Problems (1895) Results modules not included.	ClinicalTrials.gov ID	Brief Title	Record Status	Last Update
Clear Filters	NTUH	Search Column...	Select...	Select...	Search Column...	Search Column...	Select...	Select...
Open	NTUH	202409073DINC		• Entry Not Completed • Never Released		Electronic Respiratory Sound Monitoring System in Gastrointestinal Endoscopic Sedation	In Progress	2025-04-08 03
Open	NTUH	202308015MINC	PR	• Not Recently Updated	NCT06215404	Fluid Management Strategies on Blood Loss in Liver Transplantation	Released	2025-04-08 02
Open	NTUH	202408153RIND		• Entry Not Completed • Never Released		Genicular Artery Embolization (GAE) vs inTra-articular Corticosteroid Injection for Osteoarthritic Knee Pain. (GET-IN)	In Progress	2025-04-08 01

Feedback

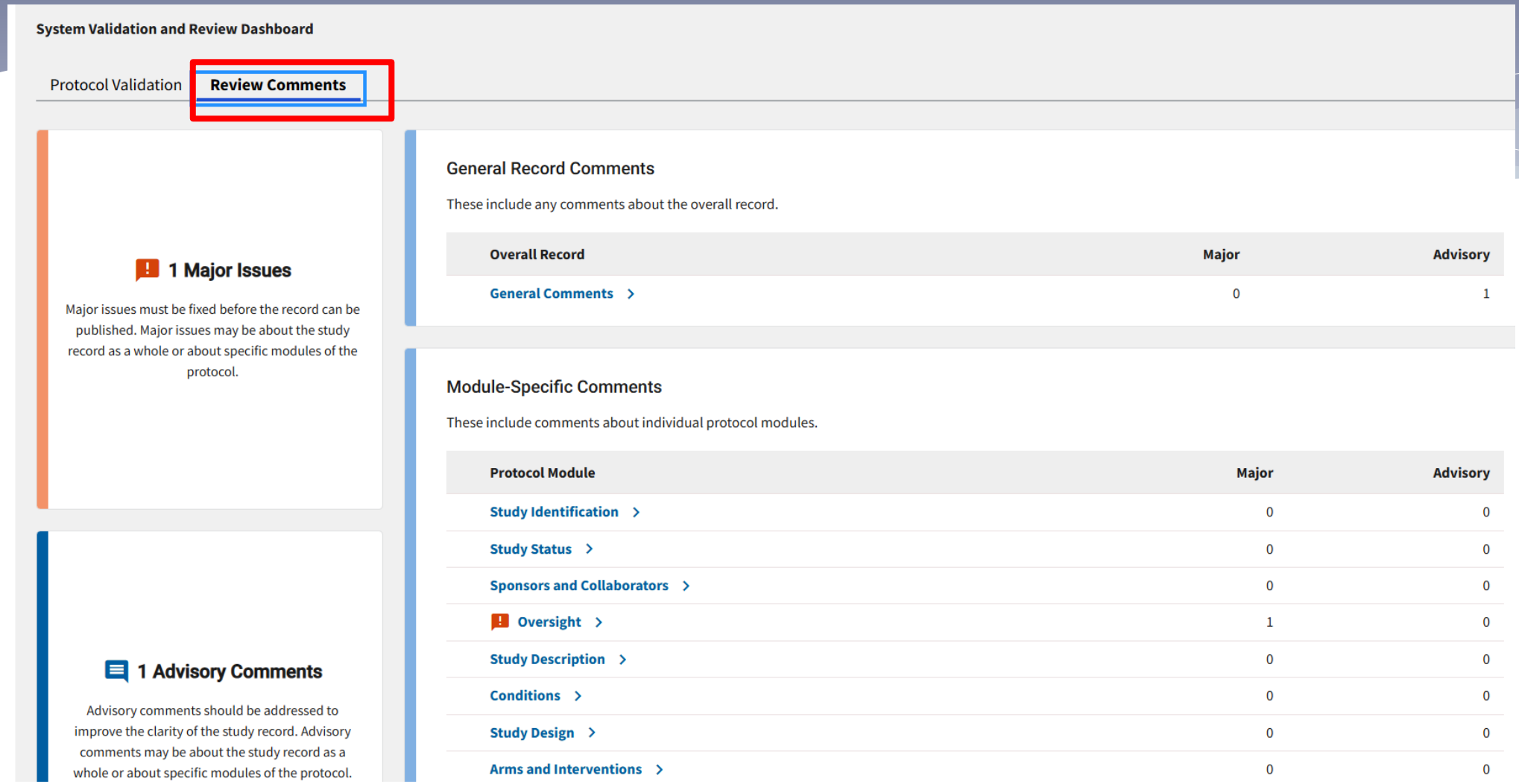
Frequently Asked Question

Publication Date

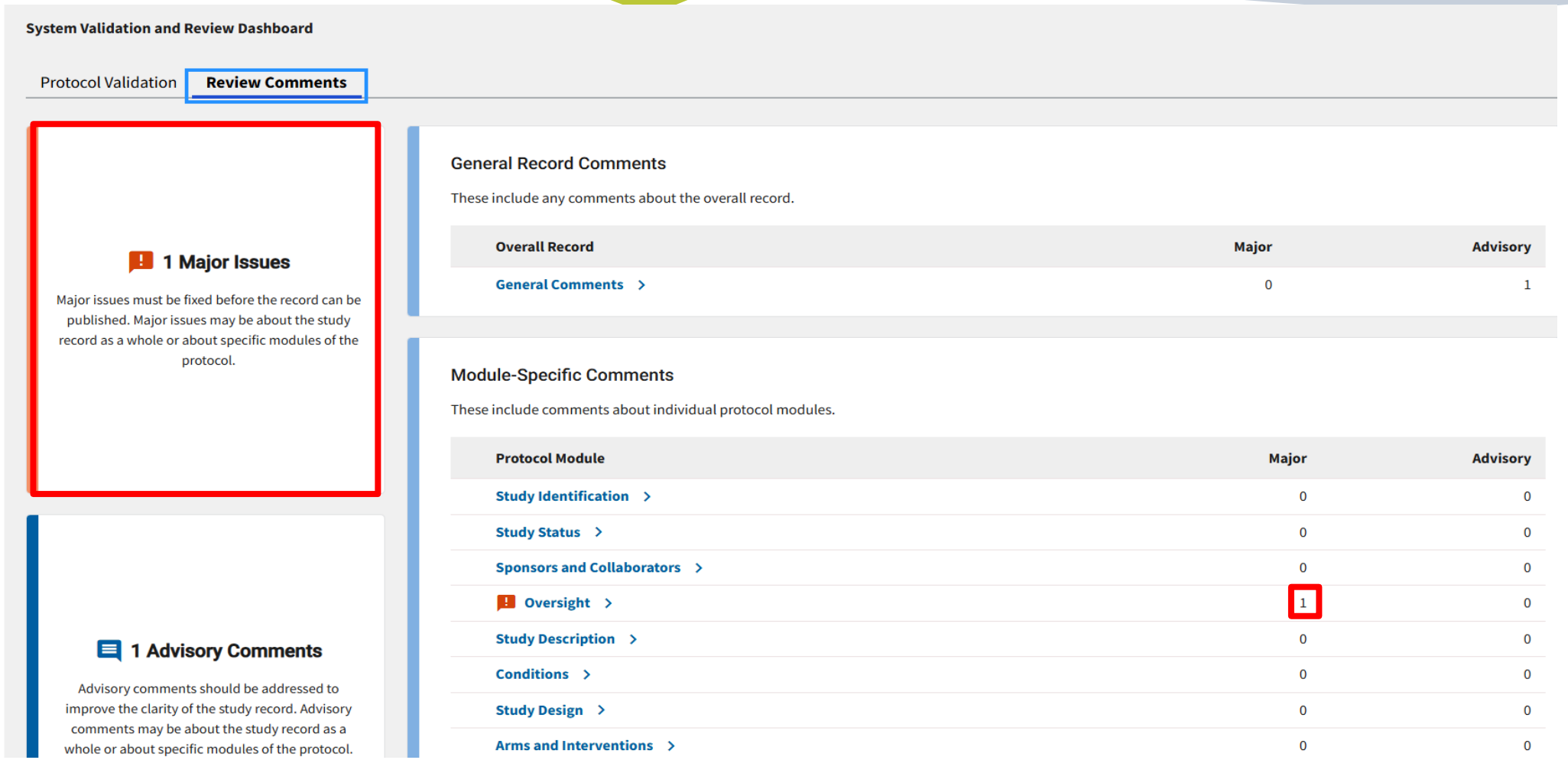
* Protocol Records are made available to the public through the ClinicalTrials.gov web site within 2 to 5 business days of release following system validation and quality assurance review. The ClinicalTrials.gov identifier (NCT number) will be assigned at that time, and will then be visible in the PRS.

* Records that contain Results may take up to 30 days.

QA Comments


System Validation and Review Dashboard
Protocol Validation
Review Comments
1 Major Issues
Major issues must be fixed before the record can be published. Major issues may be about the study record as a whole or about specific modules of the protocol.
1 Advisory Comments
Advisory comments should be addressed to improve the clarity of the study record. Advisory comments may be about the study record as a whole or about specific modules of the protocol.
General Record Comments
These include any comments about the overall record.
Overall Record
Major
Advisory
General Comments
0
1
Module-Specific Comments
These include comments about individual protocol modules.
Protocol Module
Major
Advisory
Study Identification 0 0
Study Status 0 0
Sponsors and Collaborators 0 0
Oversight 1 0
Study Description 0 0
Conditions 0 0
Study Design 0 0
Arms and Interventions 0 0

請針對問題內容逐一修改，回覆完畢後請按
”ENTRY Complete”

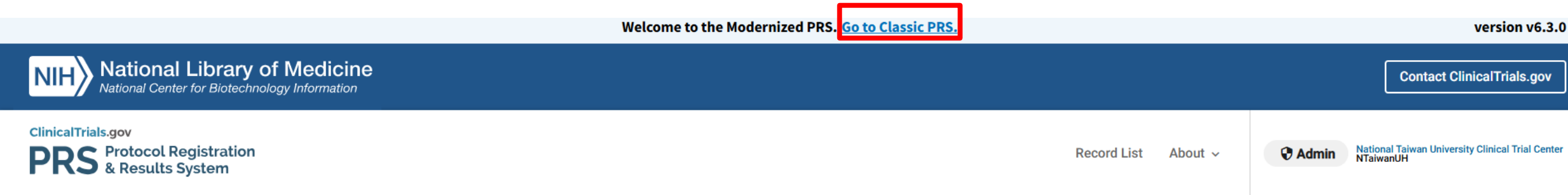


Reminder

- 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。
- 若您的計畫案為介入性臨床試驗，請務必記得要在收第一位受試者前完成登錄。
- 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)。

Reminder

- 有些較早期之資料新版網頁會無法開啟或是無法搜尋，需跳回舊網頁



Contact

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