Registration with Public Clinical Trial Registries

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Registration with Public Clinical Trial Registries

**Highlights:**

- Bases for registration of clinical trials
- Registering a trial with ClinicalTrials.gov
Objectives of Trial Registration

- Subject recruitment
- Avoid publication bias
- Public education

Bases for Public Registration
International Requirements for Trial Registration

Bases for Public Registration

- International Committee of Medical Journal Editors (ICMJE) • July 2005
- U.S. Food and Drug Administration Amendments Act (FDAAA) • September 2007
- World Medical Association Declaration of Helsinki • October 2008
International Requirements for Trial Registration

International Committee of Medical Journal Editors (ICMJE)
July 2005

U.S. Food and Drug Administration Amendments Act (FDAAA)
September 2007

World Medical Association Declaration of Helsinki
October 2008

Uniform Requirements for Manuscripts Submitted to Biomedical Journals (URM):
- Registration of a clinical trial before recruitment of the first trial subject
- ClinicalTrials.gov or other WHO-recognized “primary registries”

Clinical Trial:
Any research that progressively assigns human subjects to intervention or concurrent comparison to study the cause-and-effect relationship between a medical intervention and a health outcome

Primary Registries:
1. Australian New Zealand Clinical Trials Registry
2. Brazilian Clinical Trials Registry
3. Chinese Clinical Trial Register
4. Clinical Research Information Service (CRis) – Republic of Korea
5. Clinical Trials Registry – India
6. Cuban Public Registry of Clinical Trials
7. EU Clinical Trials Register
8. German Clinical Trials Register
9. Iranian Registry of Clinical Trials
10. ISRCTN.org
11. Japanese Primary Registries Network
12. The Netherlands National Trial Register
13. Pan African Clinical Trial Registry
14. Sri Lanka Clinical Trials Registry

Bases for Public Registration
International Requirements for Trial Registration

A Mandatory Requirement by Regulation:
- Registration of a clinical trial within 21 days after recruitment of the first trial subject
  - ClinicalTrials.gov

Applicable Clinical Trial:
Interventional trials subject to U.S. FDA regulation, including:
- Trials under an U.S. IND or IDE
- Trials having at least one site in the U.S.
- Trials involving a drug/device manufactured in the U.S.
  - Except for Phase I trials

IND – Investigational New Drug Application:
A permission by the U.S. FDA to start human testing of a new drug

IDE – Investigational Device Exemption:
A permission by the U.S. FDA to start human testing of a new medical device
International Requirements for Trial Registration

A General Ethical Principal:
- Registration of a clinical trial before recruitment of the first trial subject
- Any publicly accessible database

Clinical Trial:
Any medical research involving human subjects

Publicly Accessible Database:
- Does not specify any particular registry
- Registration with any WHO-recognized primary registries is deemed sufficient

Bases for Public Registration
Registration with ClinicalTrials.gov


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.  

- **Search for Clinical Trials**
  Find trials for a specific medical condition or other criteria in the ClinicalTrials.gov registry. ClinicalTrials.gov currently has 85,072 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.
Stage 1: Preparation for Registration

Preparation Steps 1-2-3

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Ensure the user account is ready under ClinicalTrials.gov</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 2</td>
<td>Identify the responsible party for study registration</td>
</tr>
<tr>
<td>Step 3</td>
<td>Study details (e.g. protocol) is in place</td>
</tr>
</tbody>
</table>

Registration with ClinicalTrials.gov
Stage 2: Trial Registration

Three Stages

Preparation
Registration
Verification

Organization Account under which your User Account is opened
- Administrator for HA Organization Account: Mr. Yeoh Keung (Senior Manager, Knowledge Management) (Email: yeohke@ha.org.hk; Tel: 2300 6448)

Password will be assigned by ClinicalTrials.gov and sent to user by email

Registration with ClinicalTrials.gov
Stage 2: Trial Registration

Create Protocol Record

ClinicalTrials.gov
Protocol Registration System

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: 20100210

Brief Title: A Clinical Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer

* Required by ClinicalTrials.gov

Press Continue or Cancel
Stage 2: Trial Registration - Title

**Unique Protocol ID:**
Enter sponsoring organization's unique identifier.
20100210

**Brief Title:**
Use lay language.
Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer
A Clinical 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.
RV-PC-001

**Official Title:**
Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate
Phase 2 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic

**Study Type:**
- Interventional
- Observational
- Expanded Access
- Expanded access records

**Regulated Intervention?**
Indicate whether this trial includes an intervention subject to US Food and Drug Administration regulations.
No

**IND/IDE Protocol?**
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).
No

* Required by ClinicalTrials.gov

Usually “No” for investigator-initiated study conducted only in HK

Press Continue

Registration with ClinicalTrials.gov
Stage 2: Trial Registration - Oversight

Provide information for the human subjects review board, such as an Institutional Review Board (IRB), ethics committee or equivalent group, that is responsible for the review and monitoring of this protocol. For studies involving multiple review boards, provide information only for a single board.

**Board Approval:**
- If review board approval has been granted, enter the approval number below. If the board does not assign numbers, enter date in mm/dd/yyyy format. Please send a signed board approval letter to ClinicalTrials.gov (address and instructions).
  - **Status:** Submitted, approved
  - **Approval Number:** REC 123456

**Board Name:**
- Hospital Authority Kowloon Centre/East Cluster REC
- Hong Kong Hospital Authority

**Board Contact:**
- NOTE: Incomplete review board information may delay publication of the trial on ClinicalTrials.gov.
- **Business Phone:** +852 1234 5678
- **Business Email:** abc@hkg.org.hk
- **Business Address:** Room XX, Block XX, Queen Elizabeth Hospital, 30 Gascoigne Road, Kowloon, Hong Kong

**Data Monitoring Committee?**
- Has a group been appointed to monitor safety and scientific integrity of the study?
  - **No**

**Oversight Authorities:**
- Enter, in English, country followed by organization name: [List of oversight authorities]
- **Examples:**
  - United States: Food and Drug Administration
  - Germany: Federal Institute for Drugs and Medicinal Devices
  - Hong Kong: Department of Health

*Studies requiring DOH approval: HK DOH
Studies NOT requiring DOH approval: REC*

Registration with ClinicalTrials.gov
Stage 2: Trial Registration – Sponsor

Drop-down list: choose your Username from the existing list

e.g. local / overseas research group / university
### Stage 2: Trial Registration - Summary

**Title:** A Clinical Study of Recombinant Vaccinia Virus Vaccine to...

**ID:** 20100210

<table>
<thead>
<tr>
<th>Title</th>
<th>Oversight Sponsor</th>
<th>Summary</th>
<th>Status</th>
<th>Design</th>
<th>Interventions</th>
<th>Conditions</th>
<th>Eligibility</th>
<th>Locations</th>
<th>Citations</th>
<th>Links</th>
</tr>
</thead>
</table>

#### Brief Summary

Use lay language. Include a statement of the study hypothesis.  
Brief summary of the study

#### Detailed Description

Provide a more extensive description, if desired.  
Avoid duplication of information to be recorded elsewhere, such as eligibility criteria or outcome measures.  
Detailed description of the study

* Required by ClinicalTrials.gov

Press **Submit**.
Stage 2: Trial Registration - Status

- The date you first submit this study to ClinicalTrials.gov.
- Update from time to time

Date of final data collection for primary outcome measure

- Select “Anticipated” initially
- Change to “Actual” after study completion

Date of last subject last visit

May be the same or different
Stage 2: Trial Registration - Design

**Primary Purpose:** Treatment

**Study Phase:** Phase 2

**Intervention Model:** Randomized

**Number of Arms:** 2

**Masking:** Double Blind

**Allocation:** Randomized

**Study Endpoint Classification:** Safety/Efficacy

**Enrollment:** Number of Subjects: 100

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- Select “Anticipated” initially
- Change to “Actual” after study completion
Stage 2: Trial Registration - Design

- Select “Anticipated” initially
- Change to “Actual” after study completion
Stage 2: Trial Registration - Design

Provide the primary and secondary outcome measures associated with the protocol, along with the associated time frames.

- Press "Add a primary outcome measure to this study" to enter a primary outcome measure.
- Press "Add a secondary outcome measure to this study" to enter a secondary outcome measure.

Primary Outcome Measure

Enter only one distinct outcome measure.

Response rate by RECIST criteria

Time Frame: One year

Does this outcome measure assess a safety issue? No

* Required by ClinicalTrials.gov
Stage 2: Trial Registration - Design

Provide the primary and secondary outcome measures associated with the protocol, along with the associated time frames.

Press Continue

Secondary Outcome Measure

Enter only one distinct outcome measure.

Progression-free survival and overall survival

Time Frame

Two years

Does this outcome measure assess a safety issue?

No

* Required by ClinicalTrials.gov

Registration with ClinicalTrials.gov
Stage 2: Trial Registration - Design

Provide the primary and secondary outcome measures associated with the protocol, along with the associated time frames.

### Primary Outcome Measure

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Response rate by RECIST criteria</td>
<td>One year</td>
</tr>
<tr>
<td>Safety Issue?</td>
<td>No</td>
</tr>
</tbody>
</table>

### Secondary Outcome Measures

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progression-free survival and overall survival</td>
<td>Two years</td>
</tr>
<tr>
<td>Safety Issue?</td>
<td>No</td>
</tr>
</tbody>
</table>
Stage 2: Trial Registration - Interventions

Specify the arms, if any, and their associated interventions (How to Specify Study Arms and Interventions).

Add an arm
Add an Intervention

Arm Label: *(FDAX)
Arm Label should be descriptive, yet concise, especially for later use in results posting. Examples: Metformin, Lifestyle counseling, Sugar pill
Arm A

Arm Type: *(FDAX)
Experimental

Arm Description: *(FDAX)

Interventions: *(FDAX)
There are no interventions currently listed for this study.

Continue Quit
Stage 2: Trial Registration - Interventions

Specify the arms, if any, and their associated interventions (How to Specify Study Arms and Interventions).

**Study Arms**

**ClinicalTrials.gov** Protocol Registration System

<table>
<thead>
<tr>
<th>Arm Label</th>
<th>Arm Type</th>
<th>Arm Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>* (FDAX)</td>
<td>Active Comparator</td>
<td></td>
</tr>
</tbody>
</table>

Arm Label should be descriptive, yet concise, especially for later use in results posting. Examples: Metformin, Lifestyle counseling, Sugar pill

Arm B

* Required by ClinicalTrials.gov

There are no interventions currently listed for this study.

Registration with ClinicalTrials.gov
Stage 2: Trial Registration - Interventions

Specify the arms, if any, and their associated interventions (How to Specify Study Arms and Interventions).

Press

Add an arm.
Add an Intervention

Intervention Type: Biological/Vaccines

Intervention Name: Recombinant Vaccinia Virus

Intervention Description: Description of Recombinant Vaccinia Virus

Arms: Experimental Arm A

Other Names:

Continue Quit

* Required by ClinicalTrials.gov
Stage 2: Trial Registration - Interventions

Specify the arms, if any, and their associated interventions (How to Specify Study Arms and Interventions).

<table>
<thead>
<tr>
<th>Intervention Type:</th>
<th>Intervention Name:</th>
<th>Intervention Description:</th>
<th>Arms:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug</td>
<td>S-FU</td>
<td>Description of S-FU</td>
<td>Experimental: Arm A, Active Comparator: Arm B</td>
</tr>
</tbody>
</table>

Other Names: (One per line)

* Required by ClinicalTrials.gov
### Stage 2: Trial Registration - Conditions

**ClinicalTrials.gov**

**Protocol Registration System**

**Title**: A Clinical Study of Recombinant Vaccinia Virus Vaccine to...

| ID: 201000210 |

Specify the primary condition or disease being studied, or the primary focus of the study.

Conditions are checked against the National Library of Medicine’s Medical Subject Headings (MeSH).

*Search MeSH* for a specific condition term.

#### Conditions or Focus of Study:

- Enter only condition or focus (no numbers, dashes, bullets, etc.), one per line.
  - Prostate cancer

#### Keywords:

- Enter only Keywords (no numbers, dashes, bullets, etc.), one per line.
  - Prostate cancer
  - Recombinant vaccinia virus

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*Required by ClinicalTrials.gov*
Stage 2: Trial Registration - Eligibility

Eligibility Criteria:
- Inclusion Criterion 1
- Inclusion Criterion 2
- Inclusion Criterion 3

Exclusion Criteria:
- Exclusion Criterion 1
- Exclusion Criterion 2
- Exclusion Criterion 3

Gender: Male

Age Limits: Minimum: 18 Years, Maximum: 80 Years

Is this a study of Healthy Volunteers? No

* Required by ClinicalTrials.gov
Stage 2: Trial Registration - Locations

Specify the Central Contact with overall recruiting responsibility for this study.
Specify the Study Officials/Investigators with overall scientific responsibility for this study.
Add a location to this Study.
Copy locations from the master list for this organization.
Stage 2: Trial Registration - Citations

Provide Citations of publications related to the protocol, background or results.

Citations: There are 0 citations currently listed for this study.

- Continue
- Quit
- Add
- Applicable

Press
Registration with ClinicalTrials.gov

Stage 2: Trial Registration - Citations

Protocol Record Completed

Title: A Clinical Study of Recombinant Vaccinia Virus Vaccine to...

ID: 20100210

You have reached the last data entry screen. Proceed to the next screen (Edit Protocol) to review the entire record.

Note that the data that you have entered are automatically validated by the system. Messages describing problems of varying severity (Errors, Alerts, or Notes) are included on the Edit Protocol screen beneath the relevant fields. Review each message and take the appropriate action.

Once the record is ready for review by your administrator, click on the "Complete" link near the top of the Edit Protocol Record screen to mark the record as completed. Your administrator will then "Approve" and "Release" the record, in order for the record to be submitted for final Quality Assurance review and publication on the ClinicalTrials.gov website.

Press OK to continue...
Stage 3: Verification

Three Stages

[Image: Diagram showing three stages: Preparation, Registration, Verification]

Preparation

Registration

Verification

Clinical Trials

Make sure that the records are complete and accurate

Press Complete after verification

By Principal Investigator

Registration with ClinicalTrials.gov
Stage 3: Verification

By ClinicalTrials.gov

Verification and approval by ClinicalTrials.gov takes about 7 to 10 days

Go back to www.ClinicalTrials.gov after 7 to 10 days
Stage 3: Verification

Three Stages

- Preparation
- Registration
- Verification

Verification and approval by ClinicalTrials.gov takes about 7 to 10 days

Search by ClinicalTrials.gov Study ID sent to investigator’s email address

Registration with ClinicalTrials.gov
Stage 3: Verification

Three Stages

Preparation  Registration  Verification

Verification and approval by ClinicalTrials.gov takes about 7 to 10 days

Study Posted!!

Registration with ClinicalTrials.gov
Registration with Public Clinical Trial Registries

Highlights:

• Avoiding publication bias, increasing public awareness and facilitating subject recruitment are the 3 main reasons for trial registration

• Investigators should pay attention to the requirements of the ICMJE, the US. FDA and the Declaration of Helsinki regarding trial registration

• Start your 1st registration with ClinicalTrials.gov or other recognized registries