

2018 의편협 논문작성워크숍

# Clinical Trial Registration



국립보건연구원

National Research Institute of Health

유전체센터/임상연구지원TF

박현영

# 임상시험결과를 논문으로 발표하고자 할 때 연구자들이 꼭 알아야 할 두 가지

1. 임상시험 첫 환자 enrollment이전에 WHO ICTRP registry가 승인한 사이트에 등록하여야 한다.
2. 임상시험연구결과(data)의 공유에 대해 계획하고 필요한 경우 동의서확보 등 사전준비가 필요하다.

# 순서

- 임상연구등록 왜 해야 하는가?
- 어디에 무엇을 등록하는가?
- Data Sharing Policy는 무엇이며 어떻게 대응해야 할까?

## Why Should I Register?

미국에서 수행하는  
임상연구

- It's the Law! - FDAAA
- If you want to publish your results! ICJME Requirements
- CMS Billing Rule - Mandatory reporting of NCT# on claims for items and services in “qualified clinical trails” for Medicare coverage
- Increases Research Transparency
- Helps people (patients, caregivers, providers, general public) find ongoing clinical trials

# 국내에서 수행하는 임상시험

1. 논문제출을 위해
2. 보건복지부 과제에서는 규정상 등록하라고 하니까
3. 연구자임상연구 통상진료의 보험적용
4. 연구자의 알권리

국제 학술지에서는 왜 임상시험등록을 요구하는가?

**ICMJE**

**Policies on clinical trial**

# The purpose of clinical trial registration

1. to prevent selective publication and selective reporting of research outcomes
2. to prevent unnecessary duplication of research effort
3. to help patients and the public know what trials are planned or ongoing into which they might want to enroll
4. to help give ethics review boards considering approval of new studies a view of similar work and data relevant to the research they are considering

*Retrospective registration, for example at the time of manuscript submission, meets none of these purposes.*

## 2013 Declaration of Helsinki

- **Prospective registration**
- **Timely public disclosure of results**



# ICMJE Policy on Clinical Trial Registration

▶ *Which trial should be registered if it is planned to publish the results in a journal?*

- ☑ All clinically directive trials which test any clinical hypothesis about health intervention and its outcomes

**Clinical trials begun after July 1, 2005  
must have been registered at inception.**

## *What is the ICMJE definition of a clinical trial?*

Editorials on trial registration at [www.icmje.org](http://www.icmje.org) discuss the evolution of the ICMJE definition of clinical trials. In June 2007 the ICMJE adopted the WHO's definition of clinical trial: "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. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration. The ICMJE member journals implemented the expanded definition of clinically directive trials for all trials that began enrollment on or after 1 July 2008. Those who are uncertain whether their trial meets the expanded ICMJE definition should err on the side of registration if they wish to seek publication in an ICMJE journal. The ICMJE secretariat office is unable to review specific studies to determine whether registration is necessary. If researchers or others have questions about the need to register a specific study, they should err on the side of registration or consult the editorial office of the journal they wish to publish the study in.

<http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/>

**Secondary data analyses** of primary (parent) clinical trials should not be registered as separate clinical trials, but instead should **reference the trial registration number of the primary trial**.

# ICMJE Policy on Clinical Trial Registration

## ▶ *Which registration database should I choose?*

- ☑ must be **accessible to the public at no charge**
- ☑ must be open to **all prospective registrants**  
(meaning that investigators are able to register without restriction by geographic location, academic affiliation, patient demographics, or clinical condition)
- ☑ must be managed by a not-for-profit organization
- ☑ there must be a **mechanism to ensure the validity of the registration data**
- ☑ should be electronically searchable
- ☑ must include all data from the minimal data set

# Which trials registries are acceptable to the ICMJE?

The ICMJE accepts publicly accessible registration in any registry that is a primary register of the WHO International Clinical Trials Registry Platform (ICTRP) ([www.who.int/ictrp/network/primary/en/index.html](http://www.who.int/ictrp/network/primary/en/index.html)) or in ClinicalTrials.gov, which is a data provider to the WHO ICTRP. The ICMJE endorses these registries because they meet several criteria. They are accessible to the public at no charge, open to all prospective registrants, managed by a not-for-profit organization, have a mechanism to ensure the validity of the registration data, and are electronically searchable. An acceptable registry must include the minimum 20-item trial registration dataset (<http://prsinfo.clinicaltrials.gov/trainTrainer/WHO-ICMJE-ClinTrialsgov-Cross-Ref.pdf> or [www.who.int/ictrp/network/trds/en/index.html](http://www.who.int/ictrp/network/trds/en/index.html)) at the time of registration and before enrollment of the first participant. The ICMJE considers inadequate trial registrations missing any of the 20 data fields, those that have fields that contain uninformative information, or registrations that are not made publicly accessible such as phase I trials submitted to the EU-CTR. Although not a required item, the ICMJE encourages authors to include a statement that indicates that the results have not yet been published in a peer-reviewed journal, and to update the registration with the full journal citation when the results are published.

<http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html>



# WHO ICTRP

- 58차 세계보건총회 (2005)

(2) to establish a voluntary platform to link clinical trials registers in order to ensure a single point of access and the unambiguous identification of trials with a view to **enhancing access to information** by **patients, families, patient groups** and others;

The screenshot shows the WHO ICTRP website homepage. At the top left, there is a blue button that says "Sign up for WHO updates". Below this is a navigation menu with the following items: "International Clinical Trials Registry Platform", "About", "Registry Network", "Search portal", "Unambiguous trial identification", "Reporting of findings", "News and events", "Publications", and "Clinical trials in children". The main content area is titled "Welcome to the WHO ICTRP" and contains the following text: "The mission of the WHO International Clinical Trials Registry Platform is to ensure that a complete view of research is accessible to all those involved in health care decision making. This will improve research transparency and will ultimately strengthen the validity and value of the scientific evidence base." Below this is a photograph of a group of people, with the caption "WHO/P. Viot". To the right of the photograph is the WHO ICTRP logo, which consists of a globe with a blue cross in the center and the letters "ICTRP" below it. Below the logo is a section titled "Registry Network" with a link "Search for Trials". At the bottom of the page, there is a section titled "Useful Resources" with links to "International Standards for Clinical Trial Registries", "ICTRP FAQ", and "ICTRP Glossary".

**Sign up for WHO updates**

**International Clinical Trials Registry Platform**

About

Registry Network

Search portal

Unambiguous trial identification

Reporting of findings

News and events

Publications

Clinical trials in children

## Welcome to the WHO ICTRP

The mission of the WHO International Clinical Trials Registry Platform is to ensure that a complete view of research is accessible to all those involved in health care decision making. This will improve research transparency and will ultimately strengthen the validity and value of the scientific evidence base.

*The registration of all interventional trials is a scientific, ethical and moral responsibility.*

### What is a clinical trial?

For the purposes of registration, 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. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials.

### What is trial registration?

WHO regards trial registration as the publication of an internationally-agreed set of information about the design, conduct and administration of clinical trials. These details are published on a publicly-accessible website managed by a registry conforming to WHO standards.

## Registry Network

Search for Trials

## Useful Resources

International Standards for Clinical Trial Registries

ICTRP FAQ

ICTRP Glossary

The ICMJE *encourages registration of research with non-trial designs*, but because the exposure or intervention in non-trial research is not dictated by the researchers, the ICMJE does not require it.

언제 등록해야 하는가?

**첫 피험자 enrollment 이전 !!**

IRB심의 통과 후 즉시 등록하는 것이 좋다



# 어떤 내용을 등록하는가?

## WHO Trial Registration Data Set (Version 1.3)

[Access the archive of previous versions](#)

The minimum amount of trial information that must appear in a register in order for a given trial to be considered fully registered. There are currently 24 items in the WHO Trial Registration Data Set. It is sometimes referred to as the TRDS.

<http://www.who.int/ictrp/network/trds/en/>

**1. Primary Registry and Trial Identifying Number**

Name of Primary Registry, and the unique ID number assigned by the Primary Registry to this trial.

**2. Date of Registration in Primary Registry**

Date when trial was officially registered in the Primary Registry.

**3. Secondary Identifying Numbers**

Other identifiers besides the Trial Identifying Number allocated by the Primary Registry, if any. These include:

- The Universal Trial Number (UTN)
- Identifiers assigned by the sponsor (record Sponsor name and Sponsor-issued trial number (e.g. protocol number))
- Other trial registration numbers issued by other Registries (both Primary and Partner Registries in the WHO Registry Network, and other registries)
- Identifiers issued by funding bodies, collaborative research groups, regulatory authorities, ethics committees / institutional review boards, etc.

All secondary identifiers will have 2 elements: an identifier for the issuing authority (e.g. NCT, ISRCTN, ACTRN) plus a number.

There is no limit to the number of secondary identifiers that can be provided.

**4. Source(s) of Monetary or Material Support**

Major source(s) of monetary or material support for the trial (e.g. funding agency, foundation, company, institution).

**5. Primary Sponsor**

The individual, organization, group or other legal entity which takes responsibility for initiating, managing and/or financing a study. The Primary Sponsor is responsible for ensuring that the trial is properly registered. The Primary Sponsor may or may not be the main funder.

**6. Secondary Sponsor(s)**

Additional individuals, organizations or other legal persons, if any, that have agreed with the primary sponsor to take on responsibilities of sponsorship.

A secondary sponsor may have agreed to:

- take on all the responsibilities of sponsorship jointly with the primary sponsor; or
- form a group with the Primary Sponsor in which the responsibilities of sponsorship are allocated among the members of the group; or
- act as the Primary Sponsor's legal representative in relation to some or all of the trial sites.

**7. Contact for Public Queries**

Email address, telephone number and postal address of the contact who will respond to general queries, including information about current recruitment status.

**8. Contact for Scientific Queries**

There must be clearly assigned responsibility for scientific leadership to a named Principal Investigator. The PI may delegate responsibility for dealing with scientific enquiries to a scientific contact for the trial. This scientific contact will be listed in addition to the PI.

The contact for scientific queries must therefore include:

- i. Name and title, email address, telephone number, postal address and affiliation of the Principal Investigator, and;
- ii. Email address, telephone number, postal address and affiliation of the contact for scientific queries about the trial (if applicable). The details for the scientific contact may be generic (that is, there does not need to be a named individual): e.g. a generic email address for research team members qualified to answer scientific queries.



**9. Public Title**

Title intended for the lay public in easily understood language.

**10. Scientific Title**

Scientific title of the study as it appears in the protocol submitted for funding and ethical review. Include trial acronym if available.

**11. Countries of Recruitment**

The countries from which participants will be, are intended to be, or have been recruited at the time of registration.

**12. Health Condition(s) or Problem(s) Studied**

Primary health condition(s) or problem(s) studied (e.g., depression, breast cancer, medication error).

If the study is conducted in healthy human volunteers belonging to the target population of the intervention (e.g. preventive or screening interventions), enter the particular health condition(s) or problem(s) being prevented.

**13. Intervention(s)**

For each arm of the trial record a brief intervention name plus an intervention description.

Intervention Name: For drugs use generic name; for other types of interventions provide a brief descriptive name.

- For investigational new drugs that do not yet have a generic name, a chemical name, company code or serial number may be used on a temporary basis. As soon as the generic name has been established, update the associated registered records accordingly.
- For non-drug intervention types, provide an intervention name with sufficient detail so that it can be distinguished from other similar interventions.

#### 14. **Key Inclusion and Exclusion Criteria**

Inclusion and exclusion criteria for participant selection, including age and sex. Other selection criteria may relate to clinical diagnosis and co-morbid conditions; exclusion criteria are often used to ensure patient safety.

If the study is conducted in healthy human volunteers not belonging to the target population (e.g. a preliminary safety study), enter "healthy human volunteer".

#### 15. **Study Type**

Study type consists of:

1. Type of study (interventional or observational)
2. Study design including:
  - Method of allocation (randomized/non-randomized)
  - Masking (is masking used and, if so, who is masked)
  - Assignment (single arm, parallel, crossover or factorial)
  - Purpose
3. Phase (if applicable)

For randomized trials: the allocation concealment mechanism and sequence generation will be documented.



#### 16. **Date of First Enrollment**

Anticipated or actual date of enrolment of the first participant.



#### 17. **Sample Size**

Sample Size consists of:

1. Number of participants that the trial plans to enrol in total.
2. Number of participants that the trial has enrolled.

#### 18. **Recruitment Status**

Recruitment status of this trial:

- Pending: participants are not yet being recruited or enrolled at any site
- Recruiting: participants are currently being recruited and enrolled
- Suspended: there is a temporary halt in recruitment and enrolment
- Complete: participants are no longer being recruited or enrolled
- Other



### 19. **Primary Outcome(s)**

Outcomes are events, variables, or experiences that are measured because it is believed that they may be influenced by the intervention.

The Primary Outcome should be the outcome used in sample size calculations, or the main outcome(s) used to determine the effects of the intervention(s). Most trials should have only one primary outcome.

For each primary outcome provide:

1. The name of the outcome (do not use abbreviations)
2. The metric or method of measurement used (be as specific as possible)
3. The timepoint(s) of primary interest

Example:

Outcome Name: Depression

Metric/method of measurement: Beck Depression Score

Timepoint: 18 weeks following end of treatment

### 20. **Key Secondary Outcomes**

Secondary outcomes are outcomes which are of secondary interest or that are measured at timepoints of secondary interest. A secondary outcome may involve the same event, variable, or experience as the primary outcome, but measured at timepoints other than those of primary interest.

As for primary outcomes, for each secondary outcome provide:

1. The name of the outcome (do not use abbreviations)
2. The metric or method of measurement used (be as specific as possible)
3. The timepoint(s) of interest



#### 21. **Ethics Review**

The ethics review process information of the trial record in the primary register database. It consists of:

1. Status (possible values: Not approved, Approved, Not Available)
2. Date of approval
3. Name and contact details of Ethics committee(s)

#### 22. **Completion date**

Date of study completion: The date on which the final data for a clinical study were collected (commonly referred to as, "last subject, last visit").

#### 23. **Summary Results**

It consists of:

1. Date of posting of results summaries
2. Date of the first journal publication of results
3. URL hyperlink(s) related to results and publications
4. Baseline Characteristics: Data collected at the beginning of a clinical study for all participants and for each arm or comparison group. These data include demographics, such as age and sex, and study-specific measures.
5. Participant flow: Information to document the progress and numbers of research participants through each stage of a study in a flow diagram or tabular format.
6. Adverse events: An unfavorable change in the health of a participant, including abnormal laboratory findings, and all serious adverse events and deaths that happen during a clinical study or within a certain time period after the study has ended. This change may or may not be caused by the intervention being studied.
7. Outcome measures: A table of data for each primary and secondary outcome measure and their respective measurement of precision (eg a 95% confidence interval) by arm (that is, initial assignment of participants to arms or groups) or comparison group (that is, analysis groups), including the result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data, if any.
8. URL link to protocol file(s) with version and date
9. Brief summary

#### 24. **IPD sharing statement**

Statement regarding the intended sharing of deidentified individual clinical trial participant-level data (IPD). Should indicate whether or not IPD will be shared, what IPD will be shared, when, by what mechanism, with whom and for what types of analyses. It consists of:

1. Plan to share IPD (Yes, No, Undecided)
2. Plan description

# CRIS

Clinical Research Information Service

*The only primary registry of  
WHO ICTRP in Korea*

Established in 2010



CRIS소개

검색

임상연구등록

My서비스

CRIS통계

임상연구자료실

문의 | 알림

검색할 단어 또는 문장을 입력하세요.

기본검색 | 상세검색





질병/상황 최근갱신

공지사항

+ 더보기

- CRIS 등록현황 (Registration ...)
- 네트워크 작업에 따른 서비스 일시 중지 안내...
- 워크샵으로 인한 업무지연 안내(2017.06...)
- CRIS 등록현황 (Registration ...)
- 연구정보 등록 및 수정 요류에 따른 점검 안...

CRIS 문의



043-719-8662

Q&A 문의하기

International Clinical Trials  
Registry Platform  
Search Portal

바로가기 ▶

임상연구  
온라인 교육과정

바로가기 ▶

최근 1개월 이내에 신규 등록된 임상연구

+ 더보기

- 요통의 치료 및 예방을 위한 동작감지반응 신경근전기자극... [ 2017-11-10 / KCT0002533]
- 여성의 주요우울증에 대한 노에스액(옥솔탄)의 안전성, ... [ 2017-11-10 / KCT0002532]
- 한국인 습성 연령관련황반변성 환자의 유전자형에 따른 유... [ 2017-11-10 / KCT0002531]
- 소아에서 후두마스크 슈프럼(LMA supreme)의 적... [ 2017-11-10 / KCT0002530]
- 소아에서 중심 정맥관 삽입 시 전기 자기장 유도 초음파... [ 2017-11-10 / KCT0002529]

CRIS에는 2017년 11월 14일 현재 2,511건의 임상연구정보가 등록되어 있습니다.

CRIS 통계



연구종류  
Study Type



중재종류  
Intervention Type



모집현황  
Recruitment Status



질환분류  
Disease Category



시험단계  
Phase



연구책임기관  
Sponsor

Quick Link



자주하시는질문



Q&A



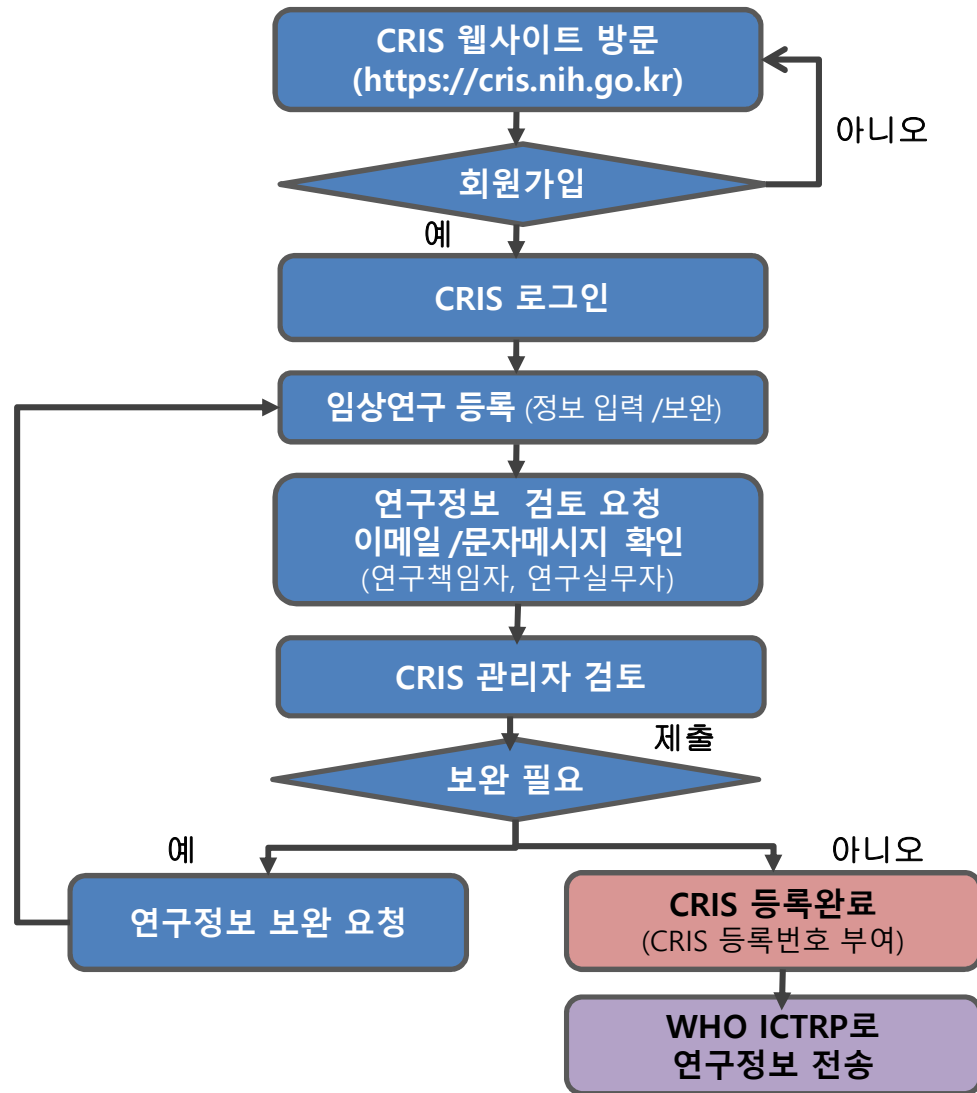
등록절차



입력항목설명집

이용약관 | 개인정보처리방침 | 저작권정책 | 운영규정 | 운영목적 | 찾아오시는길

# CRIS 임상연구 등록절차



## 입력항목

(총 12단계, 국문과 영문으로 입력)

1. 연구개요
2. 윤리심의 사항
3. 연구자 정보
4. 연구진행 현황
5. 연구비 지원기관
6. 연구 책임기관
7. 연구요약
8. 연구설계
9. 대상자 선정기준
10. 결과평가 변수
11. 연구결과 및 발표
12. 연구데이터 공유

# 연구정보 조회화면 및 이력보기

연구정보 국문	연구정보 영문	연구정보 국문·영문	이력보기	연구자/기관정보	대상자 모집기준
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상태 : 등록  
 최초제출일 : 2016/04/05      검토/등록일 : 2016/04/21      최종검신일 : 2016/04/15

[이전화면](#)

## 1. 연구개요

CRIS등록번호	KCT0001892
연구고유번호	2013-01k
요약제목	감태주정추출물 및 쌀겨주정추출물의 수면 증진 및 개선 유효성 및 안전성 평가를 위한 1주, 무작위배정, 이중맹검, 위약 대조 임상시험
연구제목	감태 주정추출물 및 쌀겨 주정추출물의 수면증진 및 개선 유효성 및 안전성 평가를 위한 1주, 무작위배정, 이중맹검, 위약대조 임상시험
연구약어명	
식약처규제연구	아니오(No)
IND/IDE Protocol여부	아니오(No)
타등록시스템 등록여부	아니오(No)
타등록시스템/등록번호	

## 2. 임상연구윤리심의

승인상태	제출 후 승인(Submitted approval)
승인번호	2013-01k
승인일	2013-03-08
위원회명	한남대학교 식품영양 장수연구소 인체시험심의위원회
자료모니터링위원회	아니오(No)

## 3. 연구자

연구책임자	
성명	조승목
직위	책임연구원
기관명	한국식품연구원
연구실무담당자	

연구정보 조회화면 예시

연구정보 국문	연구정보 영문	연구정보 국문·영문	이력보기	연구자/기관정보	대상자 모집기준
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## 연구정보비교

연구제목	건강한 남성 피험자에서 repaglinide 2 mg/metformin HCl 500 mg 복합제 투여 및 repaglinide 2 mg과 metformin HCl 500 mg 단일제 병용투여 시 안전성 및 약동학적 특성을 비교평가하기 위한 무작위배정, 공개, 단회, 교차투여 임상 시험 An open-label, randomized, single-dose, 2-way crossover trial to compare the pharmacokinetic properties after coadministration of Metformin hydrochloride and Repaglinide, or Administration of combination preparation of Metformin hydrochloride and Repaglinide in healthy male volunteers.	
요약제목	레파글리니드 2mg과 염산메트포르민 500mg 복합제 투여시와 각 성분 단일제의 병용 투여시 인체 내 약물동태를 비교하는 전향적 연구 A prospective trial to compare pharmacokinetic properties after coadministration of Repaglinide 2mg and Metformin HCl 500mg with administration of combination preparation of Repaglinide 2mg and Metformin HCl 500mg in the human body	
승인일자	2/5/2013 9:49:32	
시스템고유번호	KCT0000663	
<b>비교내용</b>		
구분	Ver. 3	Ver. 2
전체연구모집현황	연구종결(Completed)	모집추가없이 진행중(Active, not recruiting)
자료수집종료일	2013-03-24, 실제등록(Actual)	2013-04-30, 예정(Anticipated)
연구종료일	2013-04-20, 실제등록(Actual)	2013-09-30, 예정(Anticipated)
참여기관	전북대학교병원   Chonbuk National University Hospital   연구종결(Completed)   2013-03-15   실제등록(Actual)	전북대학교병원   Chonbuk National University Hospital   모집추가없이 진행중(Active, not recruiting)   2013-03-15   실제등록(Actual)

[이전화면](#)

이력보기 화면 예시

# 상세검색 및 유사연구 검색

기본검색 상세검색 유사연구검색

검색할 조건 항목하여 검색어를 입력하세요.

**연구개요**

연구제목

ORIS등록번호  다국가 연구  예  아니오

연구종류

모집현황

**관련기관**

연구비지원기관

연구비지원기관 유형  제약회사  의료기관  연구소  대학교  정부  기타

연구책임기관

연구참여기관

연구책임자

**대상질환 및 결과변수**

질환/질환명

복구질환여부  예  아니오

주요결과변수

보통결과변수

**중재연구**

임상시험단계  Phase 0  Phase 1  Phase 1/Phase 2  Phase 2  Phase 2/Phase 3  Phase 3  Phase 4

중재

**연구대상자**

성별  남성(Male)  여성(Female)

대상자연령  18세 미만  18세 이상 64세 이하  65세 이상

**주요일자**

최초제출일  -

ORIS등록일  -

최종갱신일  -

10 검색  
전체 선택 다운로드

상세검색 화면 예시

기본검색 상세검색 유사연구검색

유사도를 선택하고 연구명을 입력하세요. (띄어쓰기와 무관합니다)

SEARCH 30% 한국인당뇨병 검색

No	연구현황/유사도	연구제목
58	모집 중(Recruiting) 67%	한국인 크론병 환자의 고유 microbiome 분석 및 상호관계 규명 Analysis of microbiome in Korean Crohn's disease and establishment of its association
57	모집 중(Recruiting) 67%	한국인 크론병 코호트 구축 및 장기 추적을 통한 특성 규명 (크론병 임상연구 네트워크 구축 및 운영) Establishment of Korean Crohn's disease cohort and investigation of characteristics with longterm follow up (Establishment and management of Crohn's disease research network)
56	모집 중(Recruiting) 50%	제 2형 당뇨병 만성 합병증의 새로운 위험인자발굴을 위한 장기추적 연구 Observational Study to identify the new risk factors for the chronic complication of type 2 diabetic patients
55	모집 중(Recruiting) 50%	제2형 당뇨병 환자에서 미세알부민뇨에 대한 육미지황탕의 유효성과 안전성 - 예비임상 연구 Efficacy and safety of Yukmijihwang-tang in patients with type 2 diabetes who have microalbuminuria- a pilot study
54	연구종결(Completed) 50%	한국인의 건강한 지원자에서 Tacrolimus와 대사물의 약동학 및 약력학적 특성; CYP3A4, CYP3A5, MDR-1 유전형과의 관계 Pharmacokinetics and pharmacodynamics of Tacrolimus and its metabolites at healthy Korean volunteers: the relationship with the CYP3A4, CYP3A5, MDR-1 genotypes
53	연구종결(Completed) 50%	제 2형 당뇨병에서 채식의 임상효과 평가 및 POPs 관련 기전 연구 Evaluation of clinical effects and POPs-related mechanisms of vegan diet among Patients with Type 2 Diabetes
52	모집 중(Recruiting) 50%	한국인 정신분열병 가계에서의 염색체 18q21 부위에서의 fine mapping에 관한 예비연구 Pilot studies for fine mapping of chromosome 18q21 in the Korean schizophrenic

유사연구 검색 화면 예시

# 임상연구정보 등록

- 임상연구대상자 보호 강화, 연구수행의 투명성 및 결과의 객관성 확보 등을 위하여 보건의료기술연구개발사업 임상연구과제의 연구정보 등록
- 질병관리본부 국립보건연구원에 구축된 임상연구정보서비스(Clinical Research Information Service, CRIS, <http://cris.nih.go.kr>)에 연구비지원과제와 관련된 연구정보를 등록
- 성과보고 시, 임상연구 성과는 CRIS 등록 승인번호를 기재

## <보건의료기술 연구개발사업 관리규정> 제26조의2

주관연구기관의 장은 연구개발정보를 제26조제1항에 따라 전문기관의 장이 운영하는 보건의료기술 종합시스템에 등록하여야 한다. 다만, 보건복지부장관이 지정한 **임상연구과제의 경우에는 그 연구개발 정보**를 보건복지부장관이 지정한 전담기관에도 등록하여야 한다.



## 11. 연구결과 및 발표 (Study Results and Publication)

### 연구결과 (Results)

최종 연구대상자 수 ? (Final Enrollment Number)	<input type="text"/> 명
연구결과 등록여부 ? (Result Registerd)	연구결과가 논문으로 출판되었거나, 연구결과를 등록하시겠습니까? <input type="radio"/> 예(Yes) <input checked="" type="radio"/> 아니오(No)
결과 업로드 ? (Results Upload)	* 연구대상자 기본정보, Participant flow, 주요 연구결과, 이상반응 등이 포함된 연구결과를 정리하여 PDF 파일로 업로드하여 주십시오. <input type="text"/> <input type="button" value="찾아보기..."/> 예) JPG, GIF, PDF, HWP, DOC, ZIP 등 (단, 10M 이하)
프로토콜 URL 또는 파일 업로드 ? (Protocol URL or File Upload)	URL 입력 <input type="text"/> <input type="button" value="찾아보기..."/> 예) JPG, GIF, PDF, HWP, DOC, ZIP 등 (단, 10M 이하)
결과요약 ? (Brief Summary)	국문 (KOR) <input type="text"/> (0/4000Byte)
	영문 (ENG) <input type="text"/> (0/4000Byte)

### 연구발표 (Publication) : 본 연구의 수행으로 게재한 논문을 영문으로 작성

논문 1 <input type="button" value="추가"/>	
저자명(Author)	<input type="text"/> (0/200Byte)
논문제목(Title)	<input type="text"/> (0/4000Byte)
저널명(Journal Name)	:::선택::: <input type="text"/> (0/200Byte)
발행일(Publication Date)	<input type="text"/> <input type="text"/> vol <input type="text"/> page <input type="text"/> ~ <input type="text"/>
논문 URL(Publication URL)	<input type="text"/>

WHO ICTRP (International Clinical Trial Registry Platform)에서 요구하는 필수등록항목입니다.

CRIS 필수등록항목입니다.

## 12. 연구데이터 공유(익명화된 연구대상자 데이터) (Sharing of Study Data(Deidentified Individual-Patient Data, IPD))

결과 공유 계획 ? (Sharing Statement)	<input checked="" type="radio"/> 예(Yes) <input type="radio"/> 아니오(No)	
공유예상 시기 (Time of Sharing)	년도 <input type="text" value="▼"/> 월 <input type="text" value="▼"/>	
공유방법 ? (Way of Sharing)	국문 (KOR)	<input type="text" value="데이터 요청 시 필요한 담당자 연락처(이메일)"/>
	영문 (ENG)	<input type="text" value="데이터 요청 시 필요한 담당자 연락처(이메일)"/>

- 선택
- 요청 시 제공가능**
- 제공 불가
- 공공 리포지터리
- 기관/개인 리포지터리
- 추후 제공 예정
- 기타

- WHO ICTRP (International Clinical Trial Registry Platform)에서 요구하는 필수등록항목입니다.
- CRIS 필수등록항목입니다.

platform)에서 요구하는 필수등록항목입니다.

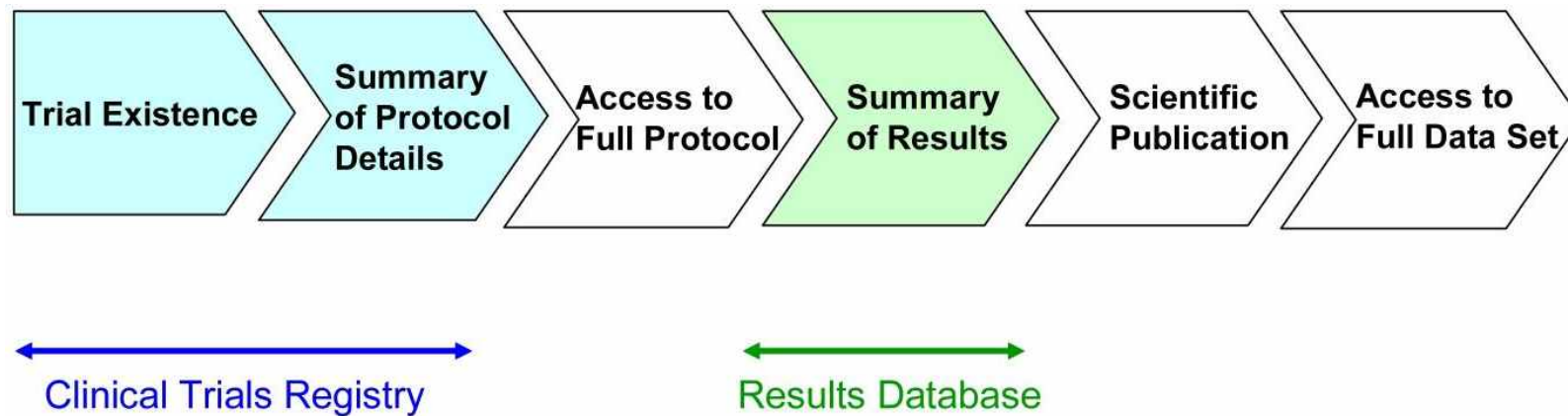
모든 내용을 작성·저장 후 나의임상연구에서 '제출' 버튼을 클릭하셔야 관리자에게 최종 제출되어집니다.

# Data Sharing

- Data sharing의 의미
- Data sharing과 관련된 정책
- 임상연구에서 ICMJE Policy



# Moving Towards Transparency of Clinical Trials



*Science. 2008; 319(5868): 1340–1342.*

## Importance

- Sharing *maximizes the value* of collected data and promotes follow-up studies of secondary research questions using existing data
- Sharing *minimizes duplicative data collection*, which in turn reduces research costs and lowers the burden on human research participants while positioning clinical trial data as a public good
- Sharing respects the contributions of the patients who consented to participate

# Policy statement

- It states our expectation that all our funded researchers should maximise access to their research data with as few restrictions as possible.
- It requires applicants whose proposed research will generate data that hold significant value as a resource for the wider research community to **submit a data management and sharing plan as part of the application process.**

The Wellcome Trust will:

review data management and sharing plans, and any costs involved in delivering them, as an integral part of the funding decision work with grant holders on an ongoing basis to support them in maximising the long-term value of key datasets resulting from their research.



# NIH Data Sharing Policy

Effective October 1, 2003

- NIH *expects* timely release and sharing of final research data for use by other researchers.
- NIH *expects* grant applicants to include a plan for data sharing or to state why data sharing is not possible, especially if \$500K or more of direct cost is requested in any single year
- NIH *expects* contract offerors to address data sharing regardless of cost

# US-NIH

## Data Sharing Policy Implementation

- If an application describes a data-sharing plan, **NIH expects that plan to be enacted.**
- If progress has been made with the data-sharing plan, then note this in the progress report.
- In the final progress report, the PI should note what steps have been taken with respect to the data-sharing plan. *In the case of noncompliance (depending on its severity and duration) NIH can take various actions to protect the Federal Government's interests.* In some instances, for example, NIH may make data sharing an explicit term and condition of subsequent awards.

# 국제의학학술지편집인협의회

ICMJE INTERNATIONAL COMMITTEE of  
MEDICAL JOURNAL EDITORS

Science, Nature, JAMA 등 전세계 3,000여 개 학술지가 ICMJE 정책 수용

2005.7

- 임상시험 등록을 한 연구만 출판가능
- 등록번호 필수제출

2016.1

- ICMJE 임상시험 결과 등록에 대해 논의함

2018.7

- 임상시험 결과에 데이터 공유에 대한 언급을 포함하여 논문원고를 제출해야 함

2019.1

- 임상시험 등록시스템에 연구결과 데이터 공유에 대한 내용이 포함된 등록번호를 제시해야 함

# 눈덩이로 덮었나? 임상결과 2년內 공개 29% 뿐

美 주요 대학병원 대상 조사결과..등록 사이트 보고 13%

이덕규 기자 | abcd@yakup.com    기사입력 2016-02-25 05:17    최종수정 2016-02-25 07:04

피험자들을 무작위 분류한 후 진행하는 임상시험은 약물 또는 의료기기의 효능 및 안전성을 평가하기 위한 이상적인(ideal) 방법으로 인식되고 있다.

하지만 미국 내 주요 대학병원들(academic medical centers)의 임상시험 공개가 여전히 미흡한 수준에 머물러 있는 것으로 나타나 관심을 모으고 있다. 임상시험 결과를 적절한 방법으로 발표 및 보고토록 하는 윤리적인 의무가 존재하거나, 심지어 법적인 필수요건으로 부과되고 있는 가운데서도 제대로 준수되지 않고 있다는 것이다.

예일대학 의대의 하란 M. 크럼홀츠 교수가 총괄한 공동연구팀은 의학저널 '브리티시 메디컬 저널'에 17일 게재한 '임상시험 결과의 발표 및 보고: 대학병원들의 횡단면적 분석' 보고서를 통해 이 같이 밝혔다.

이와 관련, 미국법은 일부 임상시험 사례들의 경우 반드시 등록하고 결과를 공개토록 할 것을 주문하고 있다.

그럼에도 불구하고, 지금까지 조사된 바에 따르면 임상시험 결과의 25~50% 정도가

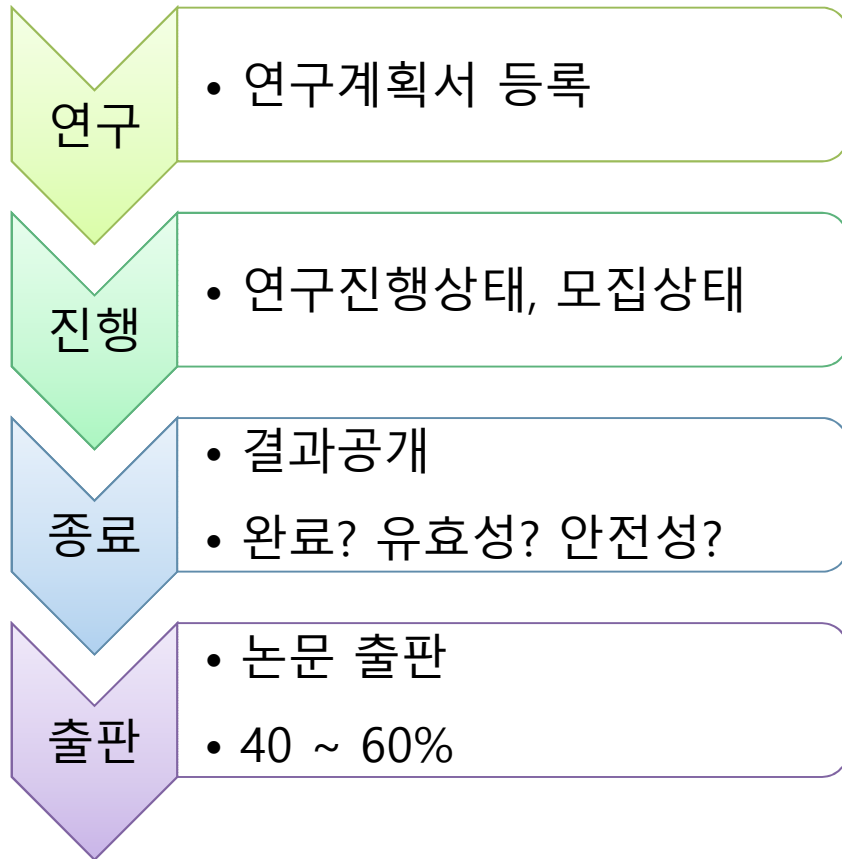
4,347 임상시험  
(2007.10-2010.9)

1,245 연구  
(29%) 종료 2년  
내 논문출판

547 연구  
(13%)  
일정기간내 연구  
결과등록

Publication and reporting of clinical trial results: cross sectional analysis across academic medical centers. *BMJ* 2016, 352, i637.

# 임상연구공개



## 국제

### 美 "임상실패정보 공개 안하면 NIH 연구비지원 중단"

기사입력 : 2016-09-19 07:44 | 수정 : 2016-09-19 07:44

바이오스펙테이터 장종원 기자



앞으로 미국에서 의약품, 의료기기 임상 시험이 실패할 경우 반드시 정보를 공개해야 한다. 정보 공개 범위도 명확해진다.

이를 지키지 않을 경우 미 국립보건원(NIH)의 연구비 지원이 중단되는 등 제재가 가해진다.

19일 외신 등에 따르면 미국 보건부(HHS)와 국립보건원(NIH)는 지난 16일(현지시간) 임상시험 정보의 가용성을 높이는 새로운 정책을 발표했다.

미국은 1997년부터 미국에서 판매할 계획이 있는 의약품의 모든 임상정보를 일반에 공개하도록 했다. 이에 따라 'Clinicaltrials.gov'라는 정보사이트가 만들어졌고 현재까지 22만 4000여건이 등록됐다.

하지만 초기단계의 임상실패 대부분이 공개되지 않으며 구체적인 임상 프로토콜이나 사망 등 부작용 정보 등이 누락되는 등 허점이 많았다. 실제로 2014년 무작위로 선정한 400건을 분석한 결과 30%가 임상 결과를 발표하지 않은 것으로 나타나기도 했다.

이번 정책은 NIH의 연구비 지원을 받는 모든 의약품(생물의약품 포함), 의료기기 등 임상 연구에 적용된다.



## Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors

1. As of 1 July 2018 manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement as described below.

2. Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration. The ICMJE's policy regarding trial registration is explained at [www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html](http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html). If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript, and updated in the registry record.

## Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors

Data sharing statements must indicate the following:

- Whether individual deidentified participant data (including data dictionaries) will be shared
- What data in particular will be shared
- Whether additional, related documents will be available (e.g., Study protocol, statistical analysis plan, etc.)
- When the data will become available and for how long
- By what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism).

**Table.** Examples of Data Sharing Statements That Fulfill These ICMJE Requirements\*

	<b>Example 1</b>	<b>Example 2</b>	<b>Example 3</b>	<b>Example 4</b>
Will individual participant data be available (including data dictionaries)?	Yes	Yes	Yes	No
What data in particular will be shared?	All of the individual participant data collected during the trial, after deidentification.	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Not available
What other documents will be available?	Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code	Study Protocol, Statistical Analysis Plan, Analytic Code	Study Protocol	Not available
When will data be available (start and end dates)?	Immediately following publication. No end date.	Beginning 3 months and ending 5 years following article publication.	Beginning 9 months and ending 36 months following article publication.	Not applicable
With whom?	Anyone who wishes to access the data.	Researchers who provide a methodologically sound proposal.	Investigators whose proposed use of the data has been approved by an independent review committee ("learned intermediary") identified for this purpose.	Not applicable
For what types of analyses?	Any purpose.	To achieve aims in the approved proposal.	For individual participant data meta-analysis.	Not applicable
By what mechanism will data be made available?	Data are available indefinitely at ( <i>Link to be included</i> ).	Proposals should be directed to xxx@yyy. To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years at a third party website ( <i>Link to be included</i> ).	Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our University's data warehouse but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing data may be found at ( <i>Link to be provided</i> ).	Not applicable

\* These examples are meant to illustrate a range of, but not all, data sharing options.

# 개인정보보호 이슈

The United States Office for Human Research Protections has indicated that provided the appropriate conditions are met by those receiving them, the sharing of deidentified individual participant data from clinical trials does not require separate consent from trial participants.

Menikoff J. Letter from Jerry Menikoff, MD, JD, Director, Office for Human Research Protections, to ICMJE Secretariat. 7 March 2017. Accessed at [http://icmje.org/news-and-editorials/menikoff\\_icmje\\_questions\\_20170307.pdf](http://icmje.org/news-and-editorials/menikoff_icmje_questions_20170307.pdf). Data Sharing Statements for Clinical Trials: A Requirement of the ICMJE EDITORIAL Annals.

## *Take-home Messages*

- 임상시험은 첫 피험자 enrollment 이전에 WHO ICTRP primary registry에 등록하여야 한다.
- 임상연구등록은 변경내역이 공개되므로 대상환자수, primary outcome 등은 신중해서 입력해야 한다.
- 2019년 이후 논문제출 시 data sharing이 평가기준의 하나이고, 정부정책 또한 원시자료 공유로 전환하고 있으므로, 연구설계단계에서부터 연구데이터 관리, 피험자 정보보호 및 동의서 등에 대한 고려가 필요하다.



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