임상연구등록시스템 및 Data Sharing Policy

국내외 정책 및 관리현황

국립보건연구원
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심혈관질환과/임상연구지원TF
박현영

순 서

- 임상연구등록 왜 해야 하는가?
- 어디에 어떻게 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 임상연구

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

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 discuss the evolution of the ICMJE definition of clinical trials. In June 2007 the ICMJE adopted the WHO's definition of clinical trial:

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.

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?

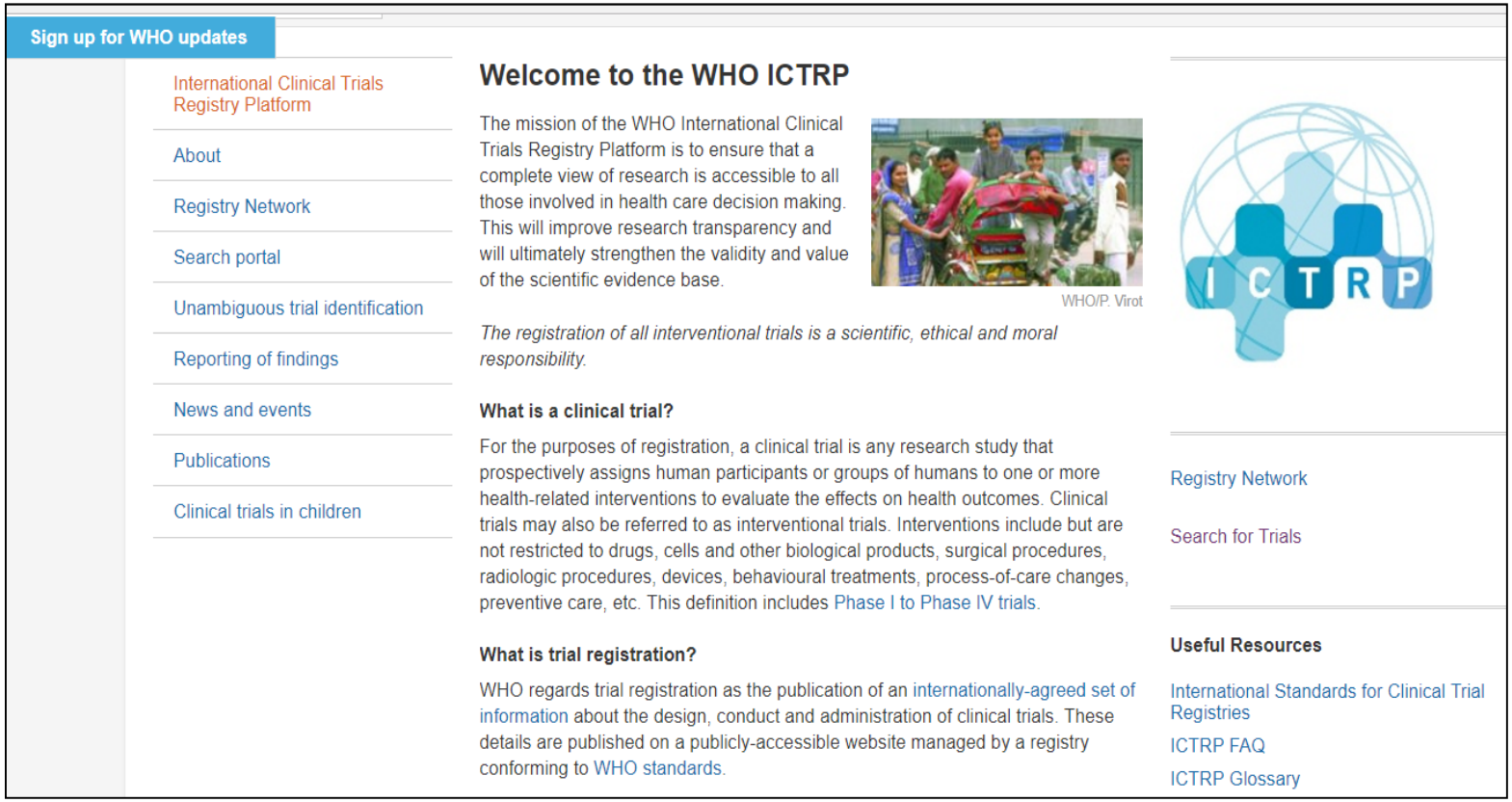
The ICMJE accepts publicly accessible registration (www.who.int/ictrp/network/primary/en/index.html) or in ClinicalTrials.gov, which is a data provider to the WHO ICTRP. The ICMJE endorses these registries because they meet several criteria. They are accessible to the public at no charge, open to all 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 (http://prsinfo.clinicaltrials.gov/trainTrainer/WHO-ICMJE-ClinTrialsgov-Cross-Ref.pdf or 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 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.

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

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

검색할 단어 또는 문장을 입력하세요.

기본검색 | 상세검색

연구검색

질병/상황 최근갱신

공지사항

+ 더보기

- CRIS 등록현황 (Registration ...
- 네크워크 작업에 따른 서비스 일시 중지 안내...
- 워크샵으로 인한 업무지연 안내(2017.06...
- CRIS 등록현황 (Registration ...
- 연구정보 등록 및 수정 오류에 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(육울탕)의 안전성, ... [2017-11-10 / KCT0002532]
- 한국인 습성 연령관련황반변성 환자의 유전자형에 따른 유... [2017-11-10 / KCT0002531]
- 소아에서 후두마스크 슈프림(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 등록되어있습니다.

CRIS 통계

연구종류 Study Type | 중재종류 Intervention Type | 모집현황 Recruitment Status | 질환분류 Disease Category | 시험단계 Phase | 연구책임기관 Sponsor

Quick Link

자주하시는질문

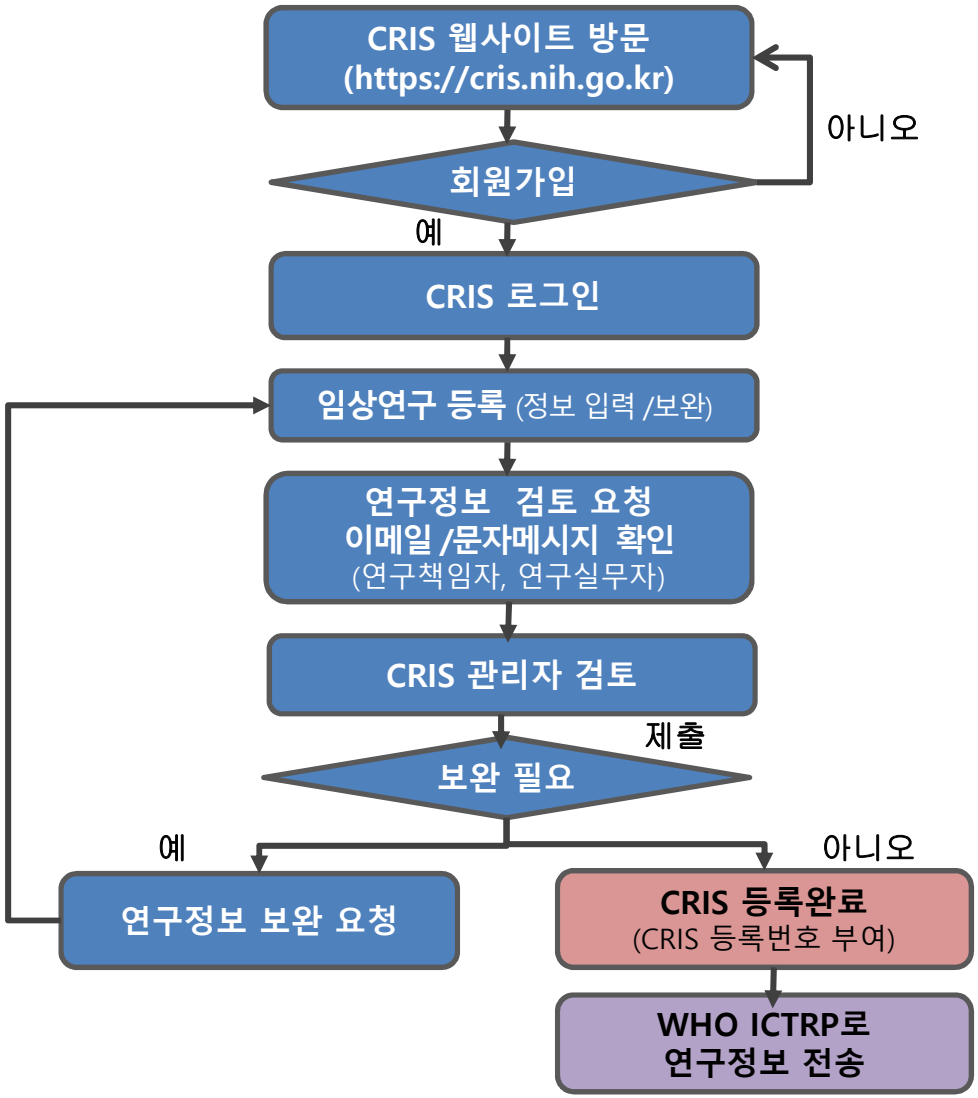
Q&A

등록절차

입력항목설명집

우)28159 충청북도 청주시 흥덕구 오송읍 오송생명2로 187 오송보건의료행정타운
Tel : 043-719-8662 | Fax : 043-719-8689

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

상 태 : 등록
최초제출일 : 2016/04/05 검토/등록일 : 2016/04/21 최종갱신일 : 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

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 임상시험 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

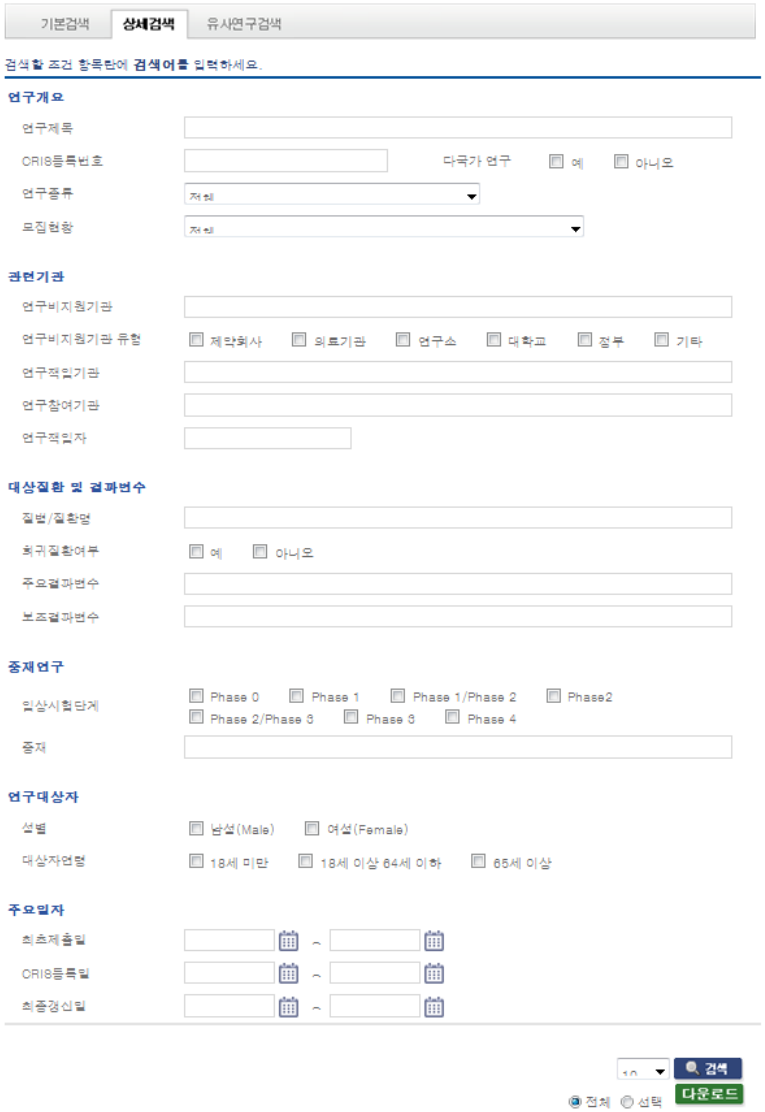
비교내용

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



상세검색 화면 예시

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 경우**에는 그 **연구개발 정보**를 보건복지부장관이 지정한 전담기관에도 **등록**하여야 한다.

연구자 주도 임상시험 급여화

(연구의 목적)
유효성과 안전성
증명 ≠ 치료

(미국)
연방정부의
승인이나 연구비지원을
받는 연구

[헬싱키선언]
치료를 겸한 의학연구에 관한 부가 원칙 (31-35)

34. 의사는 환자에게 진료 중 어떤 부분이 연구와 관계되는지 충분히 알려주어야 한다. 환자가 연구 참여를 거부하거나 참여 결정을 철회하여도 환자와 의사 관계를 저해하면 안된다.

제 목 연구자 임상시험의 보험적용 안내

1. 관련근거 : 복지부 보험급여과-3639(2015.6.30.)

2. 복지부는 위 호로 그간 해석상 논란이 되어 왔던 연구자 임상시험의 보험급여 적용에 대해 다음과 같은 경우에는 「국민건강보험 요양급여의 기준에 관한 규칙」 [별표1] '요양급여의 적용기준 및 방법' 제2호가항의 '연구목적'에 해당되지 아니함을 통보하여 온 바, 각 회에서는 소속 회원들에게 동 사항을 안내하여 주시기 바랍니다.

- 다 음 -

가. 대상기관 : 「의약품 등의 안전에 관한 규칙」 제34조의 임상시험 실시기관 지정요건을 갖는 기관

나. 목적 : 영리목적이 아닌 연구, 리서치 등 학술적 목적

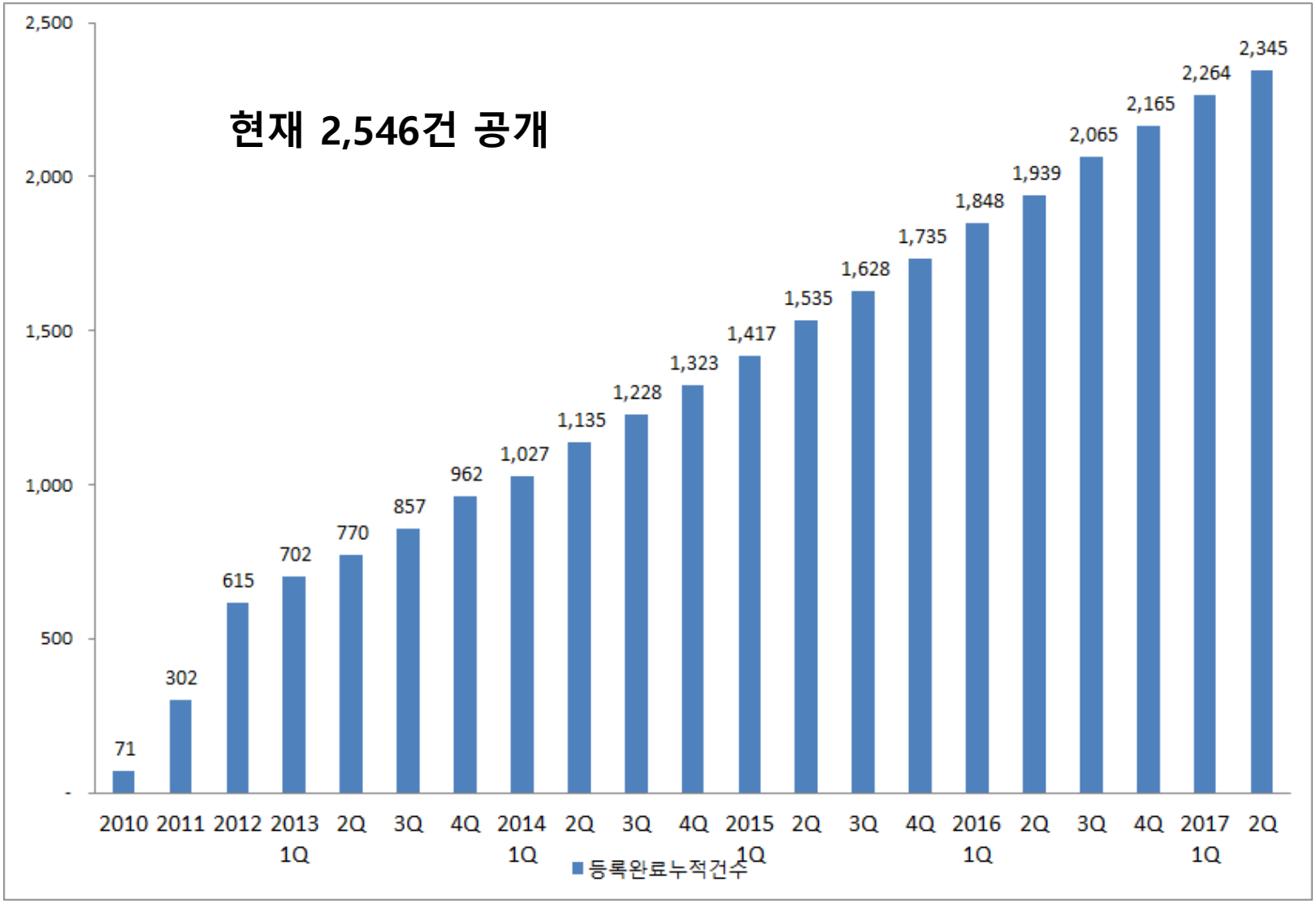
다. 절차 : 임상시험심사위원회의 승인과 환자의 동의를 받은 이후 임상시험의 전 과정(계획, protocol 작성, 임상시험 수행, data 정리 및 결과분석 · 보고 등)을 연구자가 독자적으로 주도한 경우

라. 시험대상 : 허가(신고)되어 시판중인 의약품에 대한 임상시험

마. 적용대상 : 임상시험의 시험군과 대조군 환자의 통상적인 요양급여비용 전체

바. 기타 : 아래의 경우에는 행정해석의 적용범위에서 제외함.

CRIS 등록현황: 등록완료건수



11. 연구결과 및 발표 (Study Results and Publication)

연구결과 (Results)

최종 연구대상자 수 (Final Enrollment Number)		명
연구결과 등록여부 (Result Registerd)		연구결과가 논문으로 출판되었거나, 연구결과를 등록하시겠습니까? ○ 예(Yes) ◉ 아니오(No)
결과 업로드 (Results Upload)		* 연구대상자 기본정보, Participant flow, 주요 연구결과, 이상반응 등이 포함된 연구결과를 정리하여 PDF 파일로 업로드하여 주십시오. 찾아보기... 예) JPG, GIF, PDF, HWP, DOC, ZIP 등 (단, 10M 이하)
프로토콜 URL 또는 파일 업로드 (Protocol URL or File Upload)		(0/200Byte) URL 입력 찾아보기... 예) JPG, GIF, PDF, HWP, DOC, ZIP 등 (단, 10M 이하)
결과요약 (Brief Summary)	국문 (KOR)	(0/4000Byte) 연구결과를 요약하여 기입해 주십시오.(국문)
	영문 (ENG)	(0/4000Byte) 연구결과를 요약하여 기입해 주십시오.(영문)

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

논문 1	추 가
저자명(Author)	(0/200Byte)
논문제목(Title)	(0/4000Byte)
저널명(Journal Name)	::선택:: (0/200Byte)
발행일(Publication Date)	vol page ~
논문 URL(Publication URL)	

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)	◉예(Yes) ○아니오(No)		
공유예상 시기 (Time of Sharing)	년도 월		
공유방법 (Way of Sharing)	선택 요청 시 제공가능 제공 불가능 공공 리포지터리 기관/개인 리포지터리 추후 제공 예정 기타	국문 (KOR)	데이터 요청 시 필요한 담당자 연락처(이메일)
		영문 (ENG)	데이터 요청 시 필요한 담당자 연락처(이메일)

W WHO ICTRP (Internation atform)에서 요구하는 필수등록항목입니다.

C CRIS 필수등록항목입니

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

미리보기 모두 지우기 임시 저장 취 소

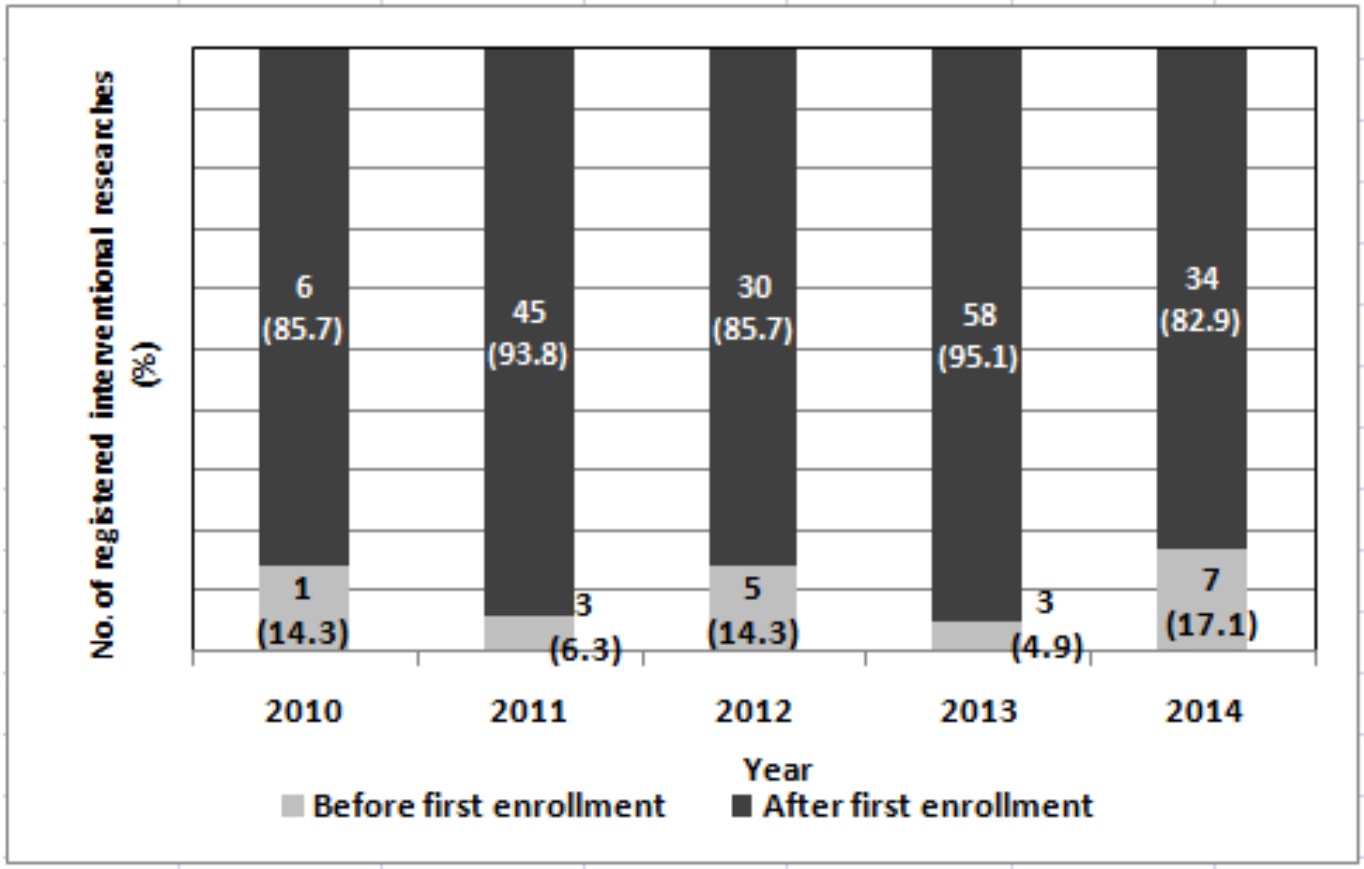
Classification of registered studies in CRIS according to research type

Research type	No. of studies	Percentage (%)	No. of studies registered into other systems
Interventional	1,690	72.1	285[†]
Observational	655	27.9	16[*]
Total	2,345	100.0	301

Classification of registered interventional studies in CRIS according to intervention type

	No. of studies registered with CRIS	Percentage (%)
Drug	807	47.8
Procedure/Surgery	224	13.3
Medical Device	224	13.3
Combined	95	5.6
Others	340	20.1
Total	1,690	100.0

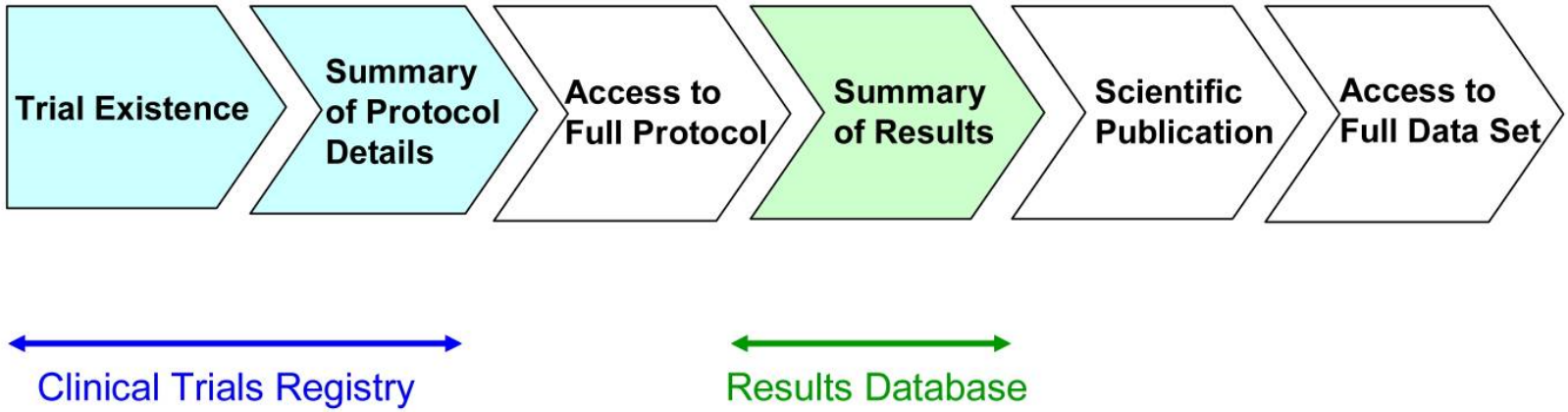
Timing of interventional research registration



Data Sharing

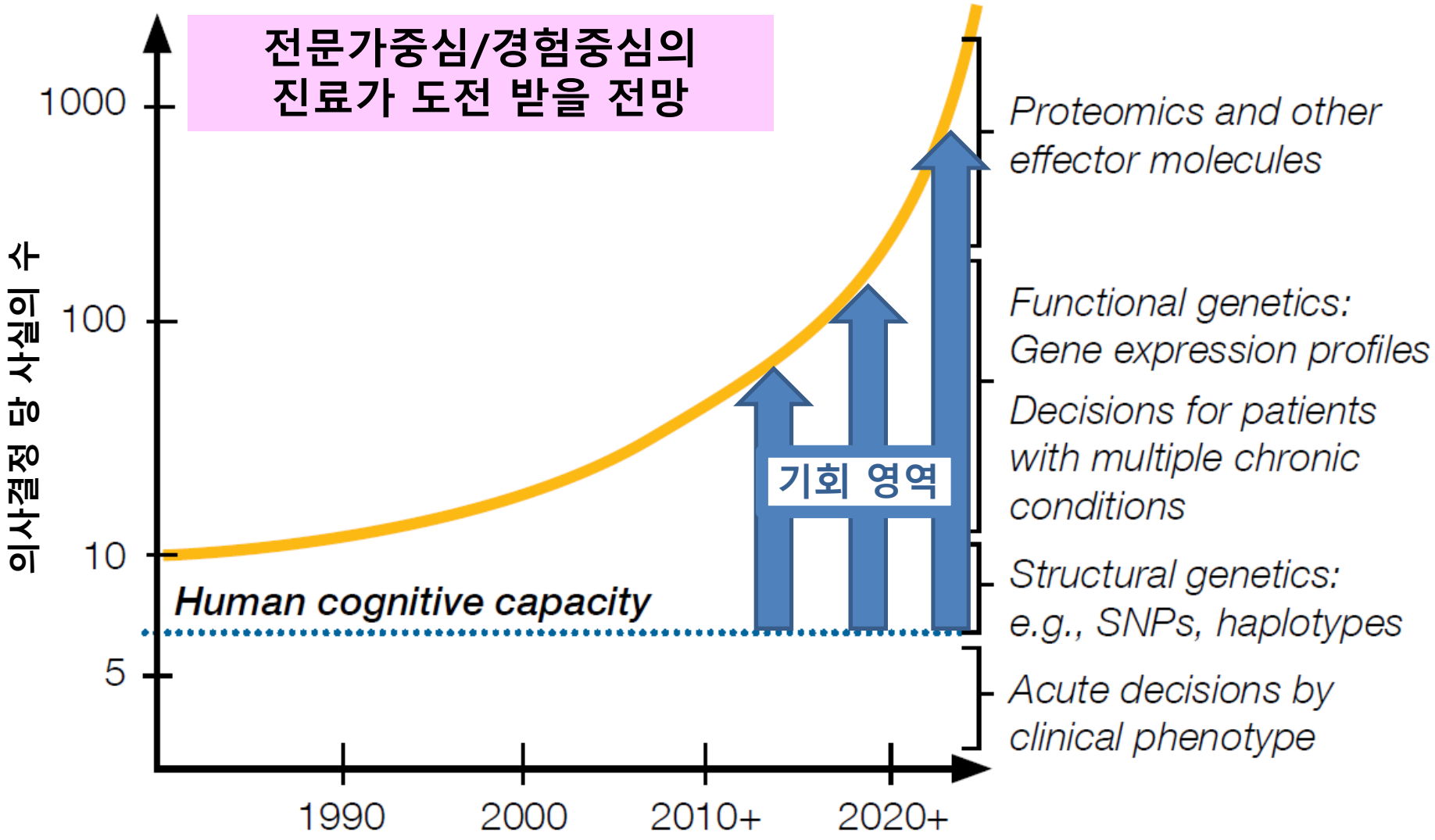
- Data sharing의 의미
- Data sharing과 관련된 정책
- 임상연구에서 ICMJE Policy

Moving Towards Transparency of Clinical Trials



Science. 2008; 319(5868): 1340–1342.

임상 및 관련정보의 폭발적인 증가



출처: William Stead; adapted by the Institute for Business Value

Data Sharing Policy

NIH Korea National Institute of Health

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

출처 : Ross, Joseph S., Harlan M. Karumholz. Ushering in a New Era of Open Science Through Data Sharing. JAMA 309(13): 1355-1356

Internationally : Data sharing is a good thing

OECD policy study

- “Publicly-funded research data are a public good produced in the public interest”

MRC policy

- Data sharing is the norm – in the public interest
- Researchers should submit DSP plans as part of grant proposals
  - ✓ The plans will be assessed as part of peer review
- Access rules should be clear
  - ✓ Transparent governance
- MRC does not prescribe the period for PI's exclusive use
  - ✓ Recognition that creators add value
- MRC will fund preservation & sharing

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

Yakup.com

인쇄하기 취소

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

http://www.yakup.com/news/index.html?mode=view&cat=16&nid=193509

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

- **연구**
  - 연구계획서 등록
- **진행**
  - 연구진행상태, 모집상태
- **종료**
  - 결과공개
  - 완료? 유효성? 안전성?
- **출판**
  - 논문 출판
  - 40 ~ 60%

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 임상시험이 실패할 경우 반드시 정보를 공개해야 한다. 정보 공개 범위도 명확해 진다.

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.

Annals of Internal Medicine

EDITORIAL

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. 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.

Annals of Internal Medicine

EDITORIAL

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).

Take-home Messages

- 임상시험은 첫 피험자 enrollment 이전에 WHO ICTRP primary registry에 등록하여야 한다.
- 임상연구등록은 변경내역이 공개되므로 대상환자수, primary outcome등은 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.

A Global Leader Pioneering Innovative Health Research

감사합니다.

국립보건연구원
National Research Institute of Health