임상시험등록과 논문게재

Clinical trial과 보고지침

NIH 국립보건연구원
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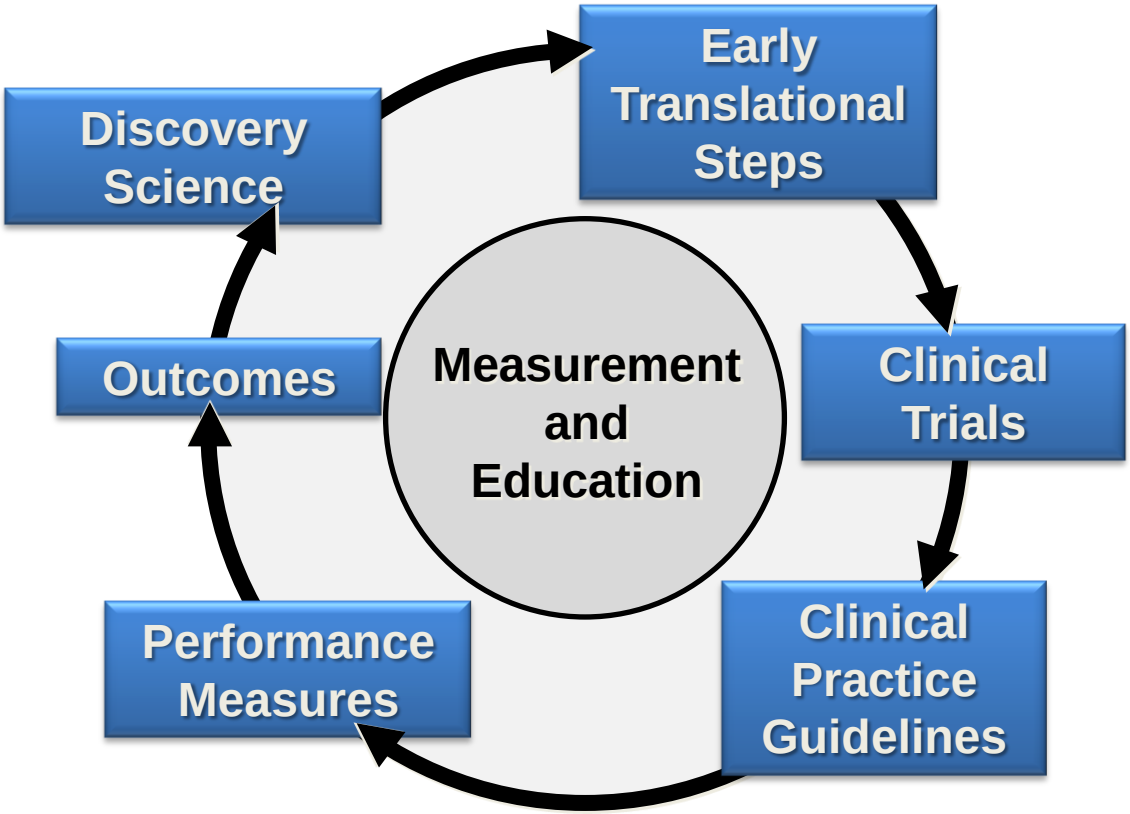
Clinical Research: "Learning health systems"

Generating Evidence to Inform Policy

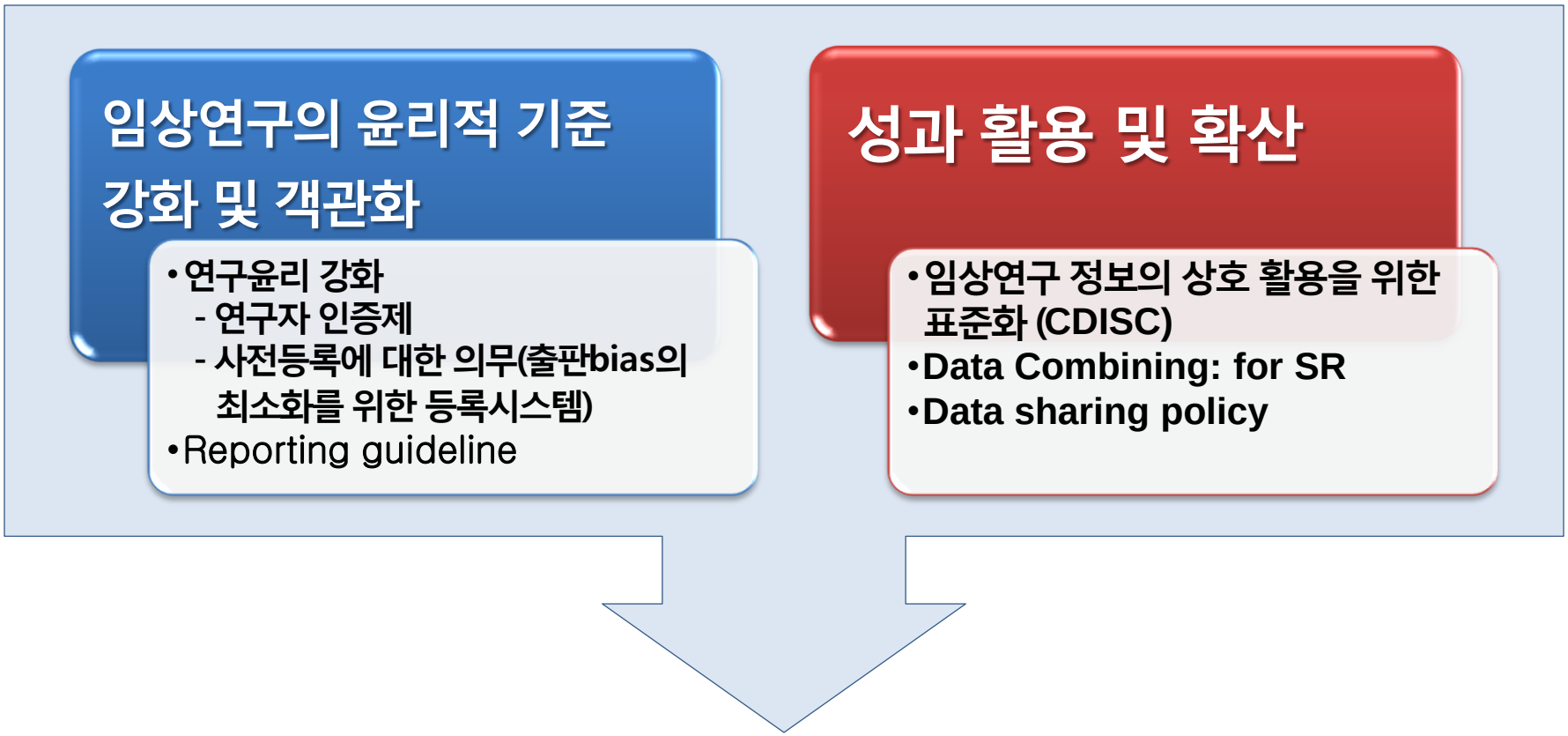


Califf RM et al, Health Affairs, 2007

임상시험

연구의 윤리적 수행과 더불어 그 **결과를 투명하게 공개**하는 것도 기본적으로 준수해야 할 윤리적 의무이다.

임상연구분야의 국제 동향



Publication Bias

- Study not published
  - ✓ Not accepted by publisher
  - ✓ Selective publication (esp. SIT)
- Only selected findings published
- Stopping a trial early for benefit

Publication Bias를 해결하려는 국제적 노력들은?

1. Clinical Trial Registration

2. Reporting Guidelines

Clinical trial registration

헬싱키선언

- 2000년, 워싱턴 개정
  - ✓ 모든 연구의 디자인이 공개적으로 접근이 되어야 하는 원칙
  - ✓ The design of all studies should be publicly available
- 2008년, 서울
  - ✓ 모든 임상시험은 첫 참여자의 모집 전에 공개적으로 접근이 되는 데이터베이스에 등록되어야 함
  - ✓ Every clinical trial must be registered in a publicly accessible data base before recruitment of the first subject

Why Registration ?

WHO Statement

- Fulfill ethical obligation to participants & the public
- Address problem of publication bias
  - ✓ Contribute to development of unbiased systematic reviews
- Advance science more quickly
  - ✓ Speed disclosure of results
  - ✓ Increase effectiveness of research funding
  - ✓ Increase participation by patients, doctors, researchers
- Increase transparency of information about trials
  - ✓ Reduce over-reporting & ambiguity

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 2005 must have been registered at inception.

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

Food and Drug Administration (FDA) Modernization Act of 1997

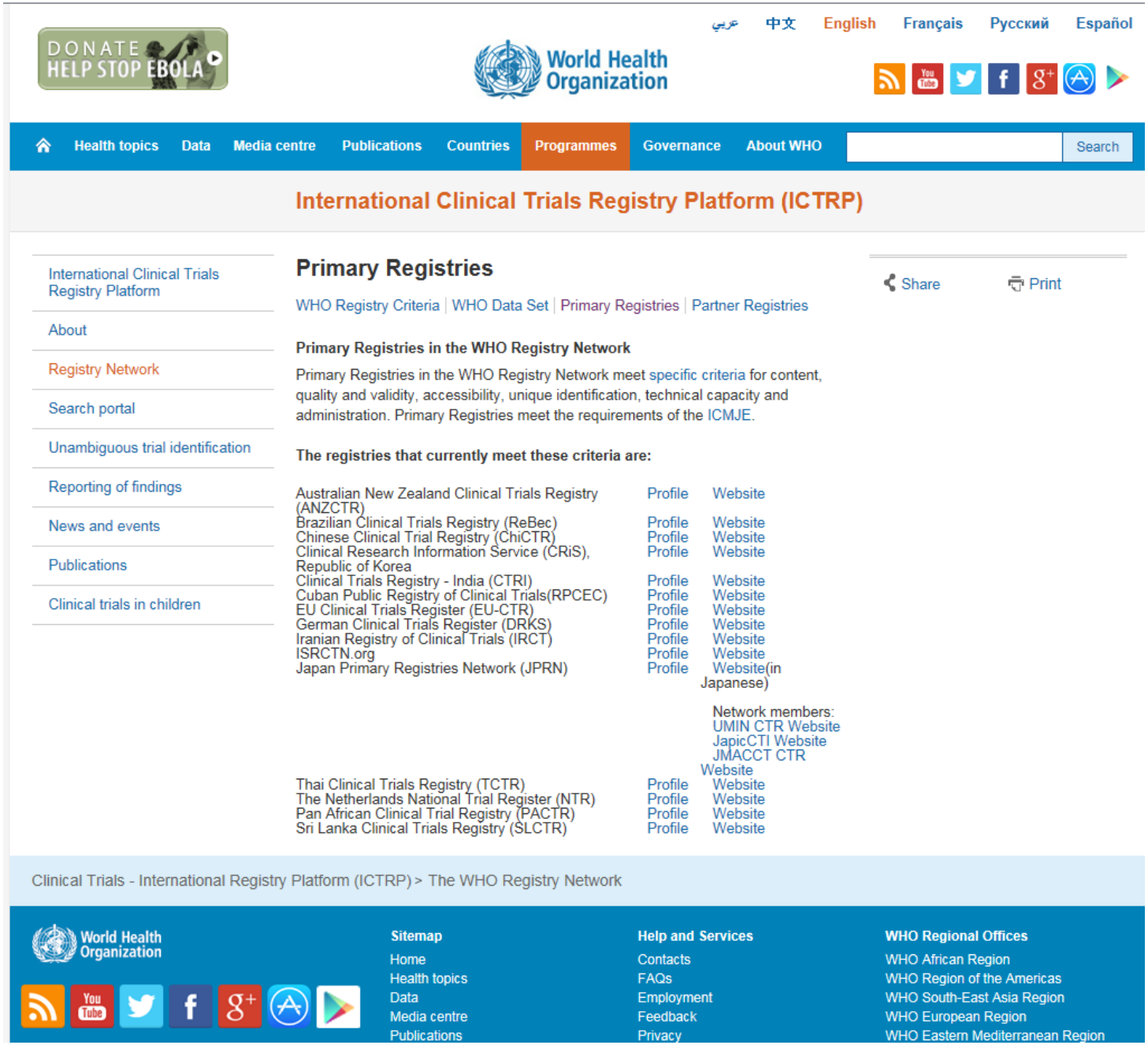
- In November 1997, Congress included a provision in the Food and Drug Modernization Act to mandate that the National Institutes of Health (NIH) establish, maintain, and **operate a public resource for information on efficacy studies of drugs, including biological drug products**, to treat serious or life-threatening diseases and conditions conducted under the FDA's investigational new drug (IND) regulations (21 CFR parts 312 and 812).
- Section 113 of the Modernization Act required that the **Clinical Trials Data Bank** contain the following information: (1) **Information about Federally and privately funded clinical trials for experimental treatments** (drug and biological products) for patients with serious or life-threatening diseases or conditions, (2) a description of the **purpose of each experimental drug**, (3) patient **eligibility criteria**, (4) a description of the **location of clinical trial sites**, and (5) a **point of contact** for patients wanting to enroll in the trial, all in a form that could be readily understood by the public.

Codes of Research Practice

- USA: Guidelines for the Conduct of Research in the Intramural Research Program at NIH
  - ✓ Registration of Clinical Trials: Clinical trials (i.e., studies evaluating the safety or efficacy of a diagnostic test or treatment intervention) should be registered with a public trials registry (e.g., www.clinicaltrials.gov).

- UK: Research Integrity Office, Code of Practice for Research
  - ✓ 3.7.13 Researchers have a duty to publish the findings of all clinical research involving human participants. In addition, it is government policy to promote public access to **information about any research and research findings affecting health and social care, including the principle that trials should appear on public registers**. In this context “trials” means all comparative studies of health interventions, not just ones conducted in a clinical setting.

ICPRT - http://www.who.int/ictrp/en/



International Clinical Trials Registry Platform (ICTRP)

- International Clinical Trials Registry Platform
- About
- Registry Network
- Search portal
- Unambiguous trial identification
- Reporting of findings
- News and events
- Publications
- Clinical trials in children

Primary Registries

Share Print

WHO Registry Criteria | WHO Data Set | Primary Registries | Partner Registries

Primary Registries in the WHO Registry Network

Primary Registries in the WHO Registry Network meet specific criteria for content, quality and validity, accessibility, unique identification, technical capacity and administration. Primary Registries meet the requirements of the ICMJE.

The registries that currently meet these criteria are:

Australian New Zealand Clinical Trials Registry (ANZCTR)	Profile	Website
Brazilian Clinical Trials Registry (ReBec)	Profile	Website
Chinese Clinical Trial Registry (ChiCTR)	Profile	Website
Clinical Research Information Service (CRiS), Republic of Korea	Profile	Website
Clinical Trials Registry - India (CTRI)	Profile	Website
Cuban Public Registry of Clinical Trials(RPCEC)	Profile	Website
EU Clinical Trials Register (EU-CTR)	Profile	Website
German Clinical Trials Register (DRKS)	Profile	Website
Iranian Registry of Clinical Trials (IRCT)	Profile	Website
ISRCTN.org	Profile	Website
Japan Primary Registries Network (JPRN)	Profile	Website(in Japanese) Network members: UMIN CTR Website JapicCTI Website JMACCT CTR Website
Thai Clinical Trials Registry (TCTR)	Profile	Website
The Netherlands National Trial Register (NTR)	Profile	Website
Pan African Clinical Trial Registry (PACTR)	Profile	Website
Sri Lanka Clinical Trials Registry (SLCTR)	Profile	Website

World Health Organization

International Clinical Trials Registry Platform
Search Portal

Home | Advanced Search | List By | Search Tips | UTN | ICTRP website | Contact us

Example: liver cancer OR breast cancer NOT genetic | Search | Search tips

Welcome

- The Clinical Trials Search Portal provides access to a central database containing the trial registration data sets provided by the registries listed on the right. It also provides links to the full original records.
- To facilitate the unique identification of trials, the Search Portal bridges (groups together) multiple records about the same trial. More information
- Please note: This Search Portal is not a clinical trials registry. How to register a trial
- For mobile users, please use this link http://apps.who.int/trialsearch/ictrpmob.aspx. It can be opened from any smartphone
- It is now possible to export the results of the search into XML. More information
- Crawling the ICTRP database now requires a username/password. To request access to the crawling pages please send an email to ictrpinfo@who.int (This service is currently disabled)
- Call for public Consultation (closed): WHO Statement on Public Disclosure of Clinical Trial Results More information

Data Providers

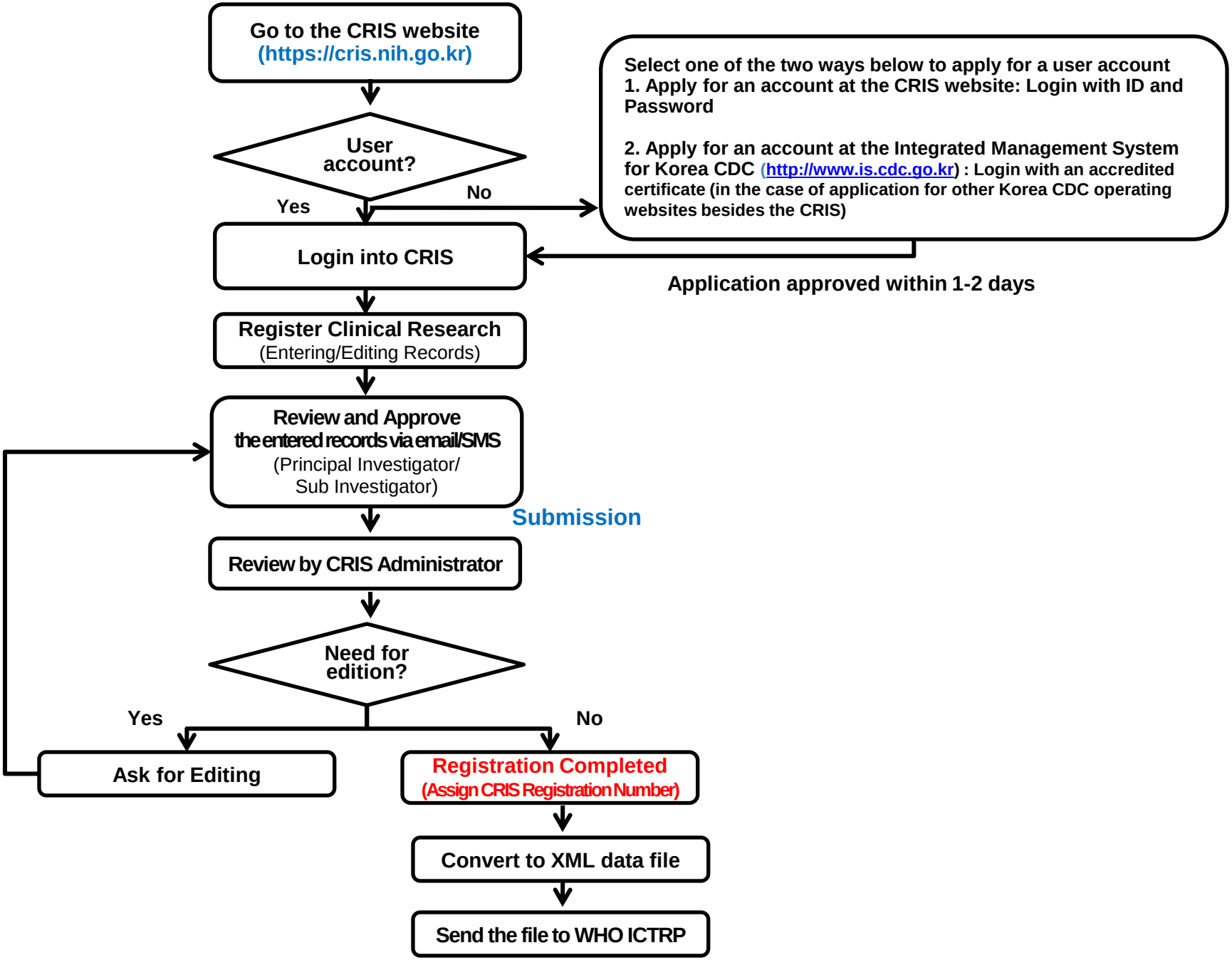
Data sets from data providers are updated every Wednesday evening according to the following schedule:
Every week:

- Australian New Zealand Clinical Trials Registry, last data file imported on **16 March 2015**
- Chinese Clinical Trial Registry, last data file imported on **16 March 2015**
- ClinicalTrials.gov, last data file imported on **16 March 2015**
- EU Clinical Trials Register (EU-CTR), last data file imported on **16 March 2015**
- ISRCTN, last data file imported on **16 March 2015**
- The Netherlands National Trial Register, last data file imported on **16 March 2015**

Every 4 weeks:

- Brazilian Clinical Trials Registry (ReBec), last data file imported on **16 March 2015**
- Clinical Trials Registry - India, last data file imported on **2 March 2015**
- Clinical Research Information Service - Republic of Korea, last data file imported on **3 March 2015**
- Cuban Public Registry of Clinical Trials, last data file imported on **3 March 2015**
- German Clinical Trials Register, last data file imported on **3 March 2015**
- Iranian Registry of Clinical Trials, last data file imported on **3 March 2015**
- Japan Primary Registries Network, last data file imported on **3 March 2015**
- Pan African Clinical Trial Registry, last data file imported on **9 March 2015**
- Sri Lanka Clinical Trials Registry, last data file imported on **2 March 2015**
- Thai Clinical Trials Register (TCTR), last data file imported on **3 March 2015**

http://cris.nih.go.kr


Go to the CRIS website
(https://cris.nih.go.kr)
User account?
Yes
No
Select one of the two ways below to apply for a user account
1. Apply for an account at the CRIS website: Login with ID and Password
2. Apply for an account at the Integrated Management System for Korea CDC (http://www.is.cdc.go.kr) : Login with an accredited certificate (in the case of application for other Korea CDC operating websites besides the CRIS)
Login into CRIS
Application approved within 1-2 days
Register Clinical Research
(Entering/Editing Records)
Review and Approve
the entered records via email/SMS
(Principal Investigator/
Sub Investigator)
Submission
Review by CRIS Administrator
Need for edition?
Yes
No
Ask for Editing
Registration Completed
(Assign CRIS Registration Number)
Convert to XML data file
Send the file to WHO ICTRP

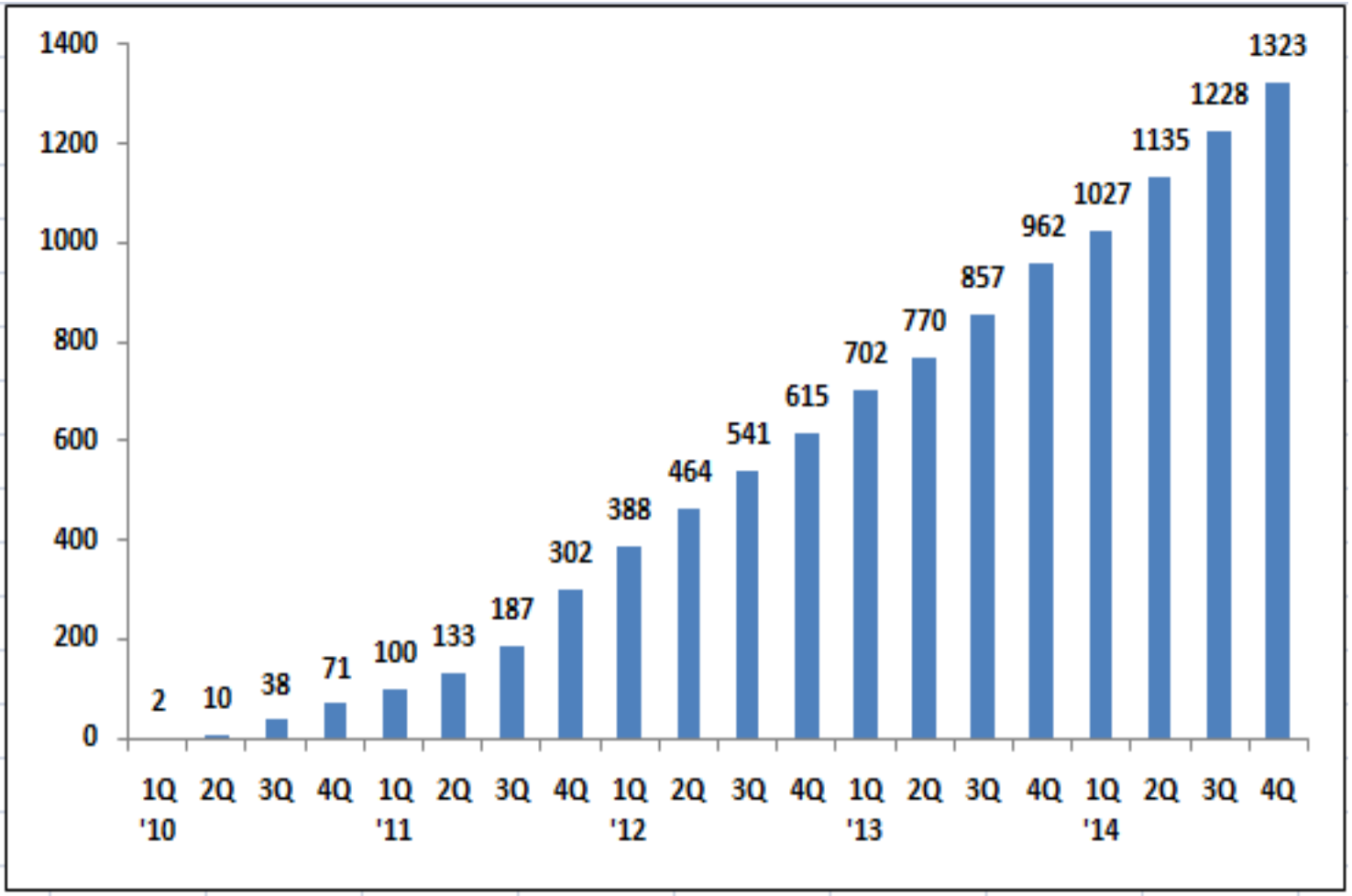
임상연구정보 등록

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

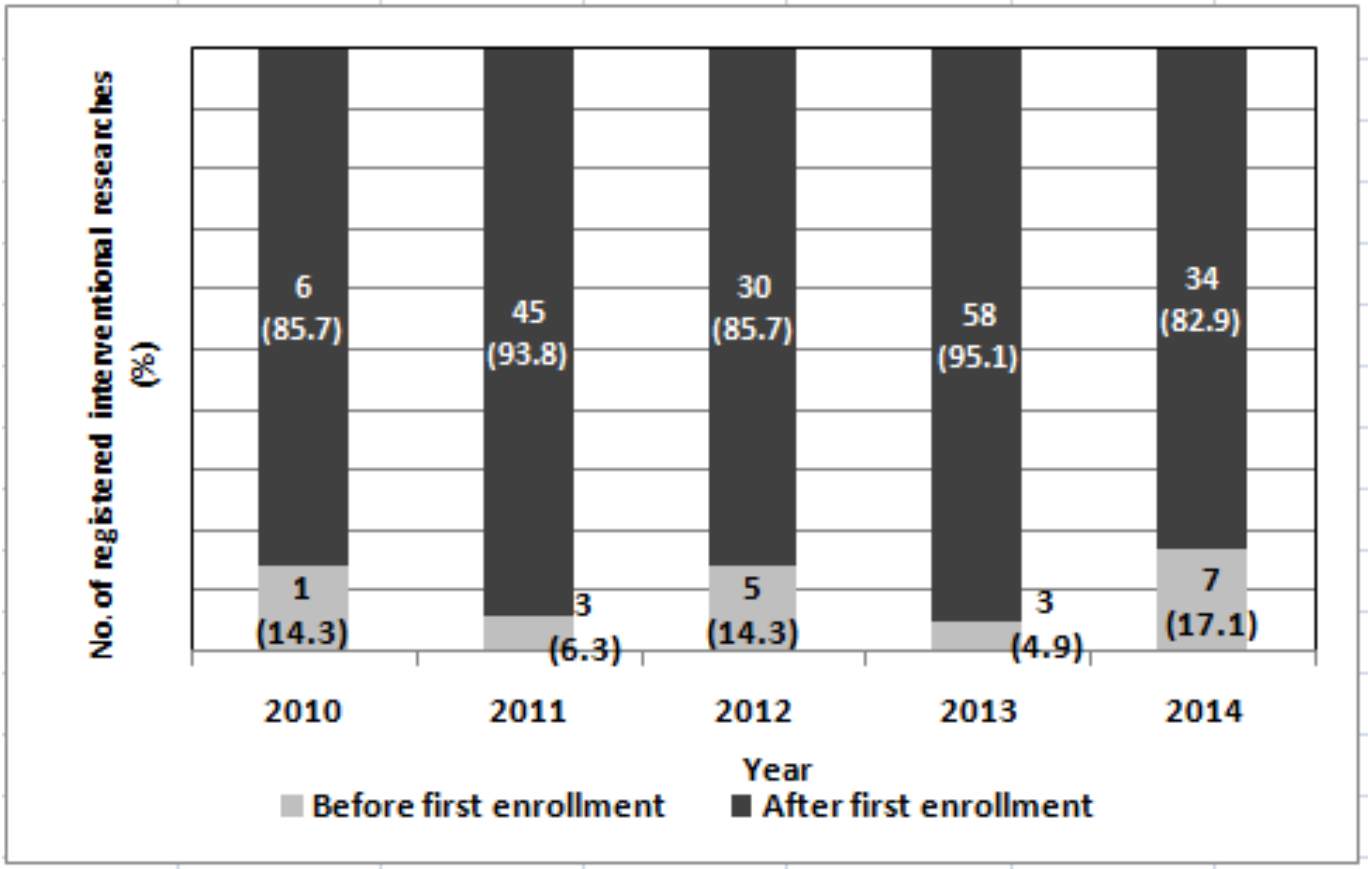
<보건의료기술 연구개발사업 관리규정> 제26조의2

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.

Accumulated number of registered clinical researches into the CRIS



Timing of interventional research registration



Reporting guideline

Why reporting guideline for clinical research ?

- 부적절한 report로는 연구의 질과 의미(상관성)를 평가하기 어렵다.
- Publication bias
  - ✓ Reporting bias (authors)
  - ✓ Study publication bias (Publisher)
- Meta분석 등 연구결과의 활용이 어렵다.

Publication Bias

- Study not published
  - ✓ Not accepted by publisher
  - ✓ Selective publication (esp. company-sponsored trials)
- Only selected findings published
- Stopping a trial early for benefit

Some history of reporting guidelines developed by consensus

1993-94	SORT	RCT
1994	Asilomar	RCT
1995-96	**CONSORT**	**RCT**
1996-99	QUOROM	SR/M-A of RCTs
1997-00	MOOSE	M-A of obs. studies
1999-01	**CONSORT II**	**RCT**
2000-03	STARD	Diagnostic test
2003-04	TREND	Non-RCT/Behavioural
2001-05	REMARK	Biomarker(cancer)
2004	**STROBE**	**Observational**
2005	QUOROM II	SR/M-A of RCTs
2010	**CONSORT2010**	**RCT**

SORT:Standardized Reporting of Trials, QUOROM;Quality of Reporting of Meta-analyses

Reporting Guidelines for Clinical Research

연구 종류에 따른 국제적인 research reporting guideline이 개발되었음

STROBE

- **Strengthening the Reporting of Observational Studies in Epidemiology**

STREGA

- **Strengthening the Reporting of Genetic Association Studies**

CONSORT

- **CONsolidated Standards of Reporting Trials**

STARD

- **Reporting of diagnostic accuracy studies**

PRISMA

- **Reporting of systematic reviews**

MOOSE

- **Reporting of meta-analyses of observational studies**

EQUATOR

- Enhancing the Quality and Transparency of Health Research
- 국제적인 보건의료 reporting의 표준을 위한 networking

CONSORT statement와 관련된 설명 및 예시는 모두 공식사이트 및 publication된 논문으로부터 인용한 것입니다.

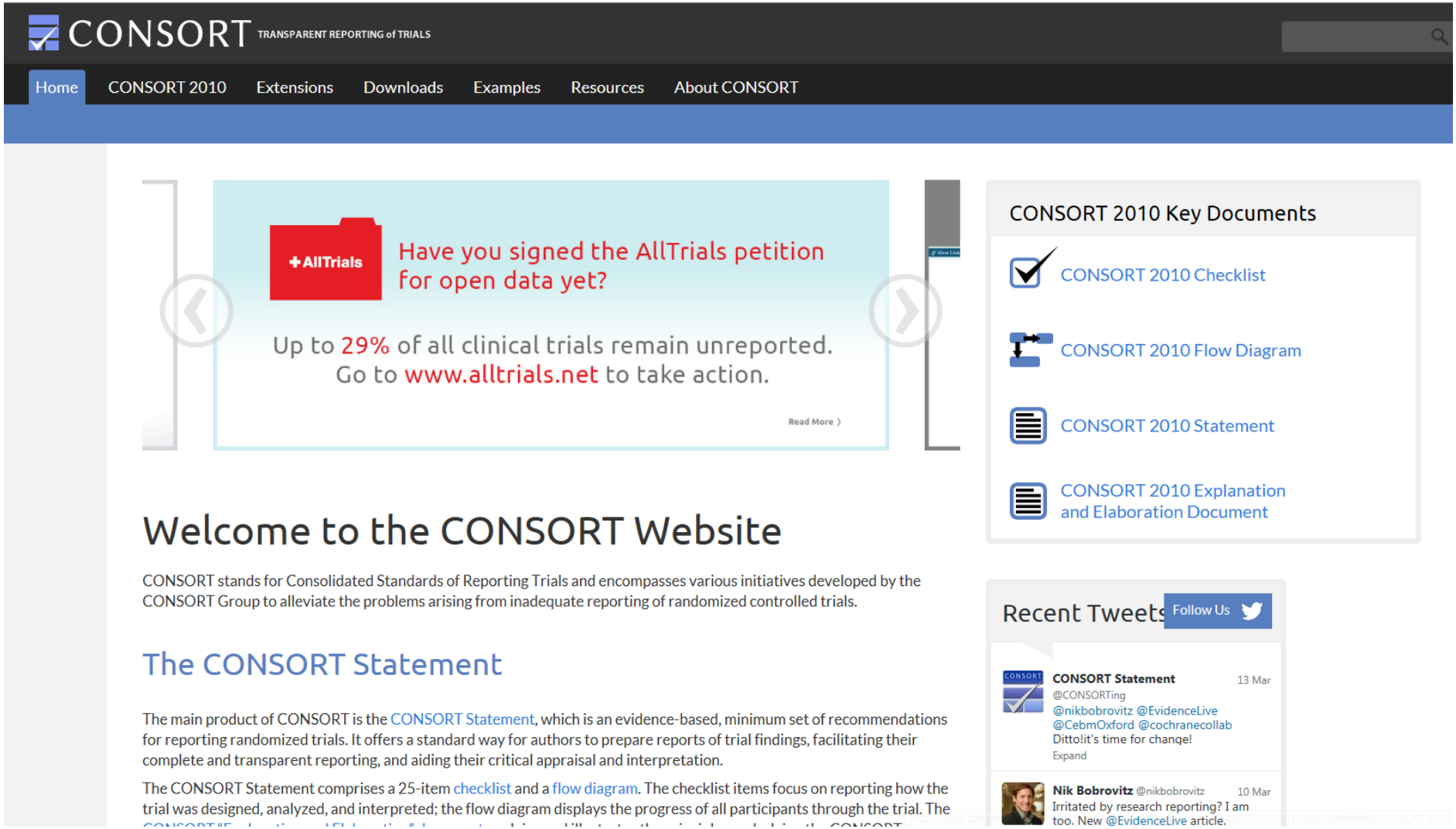
Using the CONSORT Statement

However, because the guidelines represent a consensus agreed through successive drafts by the CONSORT Group, they should not be edited or modified in any way, although it is acceptable to publish portions (e.g., the summary).

http://www.consort-statement.org/consort-statement/citing-and-using-consort/

CONSORT (CONsolidated Standards of Reporting Trials) Statement

http://www.consort-statement.org



CONSORT statement

- Object
  - ✓ To improve the reporting of a randomized controlled trial (RCT), enabling readers to understand a trial's design, conduct, analysis and interpretation
  - ✓ To assess the validity of its results.
- By using a checklist and flow diagram.

CONSORT 2010 checklist (25 items)

Korea National Institute of Health

TITLE & ABSTRACT

INTRODUCTION

- Background & Objectives

METHODS

- Trial design
- Participants
- Interventions
- Outcomes
- Sample size
- Randomization
  - **Sequence generation**
  - **Allocation concealment**
  - **Implementation**
- Blinding
- Statistical methods

RESULTS

- Participant flow
- Recruitment
- Baseline data
- Numbers analyzed
- Outcomes and estimation
- Ancillary analyses
- Harms (Adverse events)

DISCUSSION

- Limitations
- Generalisability
- Interpretation

OTHRT INFORMATION

- Registration
- Protocol
- Funding

Title

- To help ensure that a study is appropriately indexed and easily identified, authors should use the word **“randomised”** in the title to indicate that the participants were randomly assigned to their comparison groups.
- Example
  - ✓ “Smoking reduction with oral nicotine inhalers: double blind, randomised clinical trial of efficacy and safety.”(BMJ. 2000;321:329-33.)

Method: Trial Design

- **Description of trial design (such as parallel, factorial) including allocation ratio**
- Example
  - ✓ This was a multicenter, stratified (6 to 11 years and 12 to 17 years of age, with imbalanced randomisation [2:1]), double-blind, placebo-controlled, parallel-group study conducted in the United States (41 sites) *(Pediatrics 2009;123:e770-e776)*

Method: Study settings

- **Settings and locations where the data were collected**
- Example
  - ✓ The study took place at the antiretroviral therapy clinic of Queen Elizabeth Central Hospital in Blantyre, Malawi, from January 2006 to April 2007. Blantyre is the major commercial city of Malawi, with a population of 1 000 000 and an estimated HIV prevalence of 27% in adults in 2004. *(BMJ 2009;338:1867-75)*

Method: Sample size

- **How sample size was determined**
- Example
  - ✓ To detect a reduction in PHS (postoperative hospital stay) of 3 days (SD 5 days), which is in agreement with the study of Lobo et al. with a **two-sided 5% significance level and a power of 80%,** a sample size of 50 patients per group was necessary, **given an anticipated dropout rate of 10%**. To recruit this number of patients a 12-month inclusion period was anticipated. *(Trials 2009;10:50)*

Method: Randomisation
sequence generation

- **Method used to generate the random allocation sequence**
- **Examples**
  - ✓ Independent pharmacists dispensed either active or placebo inhalers **according to a computer generated randomisation list**. *(BMJ.2000;321:329-33)*
  - ✓ “For allocation of the participants, a computer-generated list of random numbers was used. *(Obstet Gynecol 2008;111:639-47)*

Method: Blinding

- **If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how**
- **Example**
  - ✓ Whereas patients and physicians allocated to the intervention group were aware of the allocated arm, outcome assessors and data analysts were kept blinded to the allocation. *(Mayo Clin Proc 2008;83:747-57)*

Results: Participant Flow

- **A diagram is strongly recommended.**
- Item 13a - For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

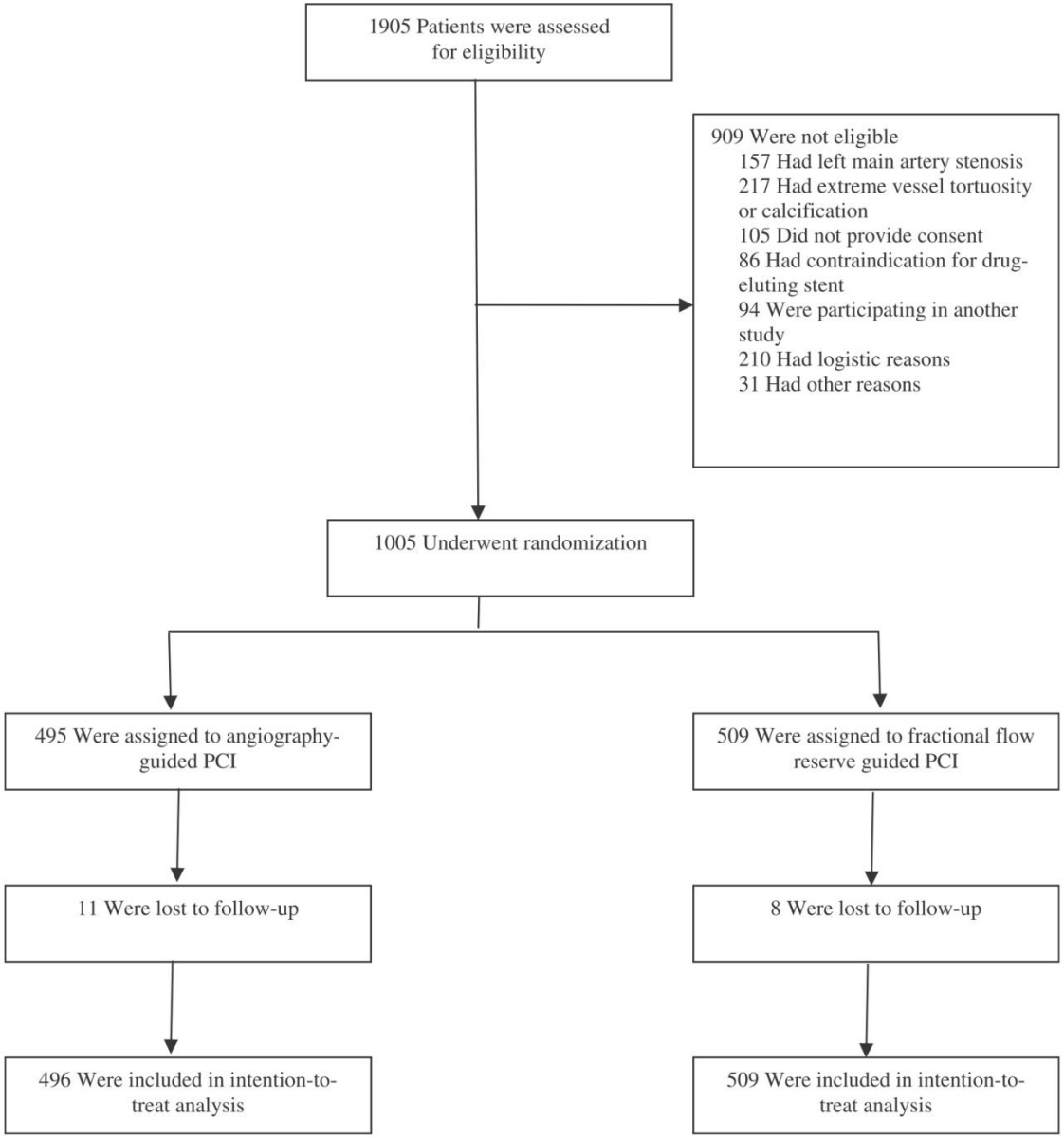
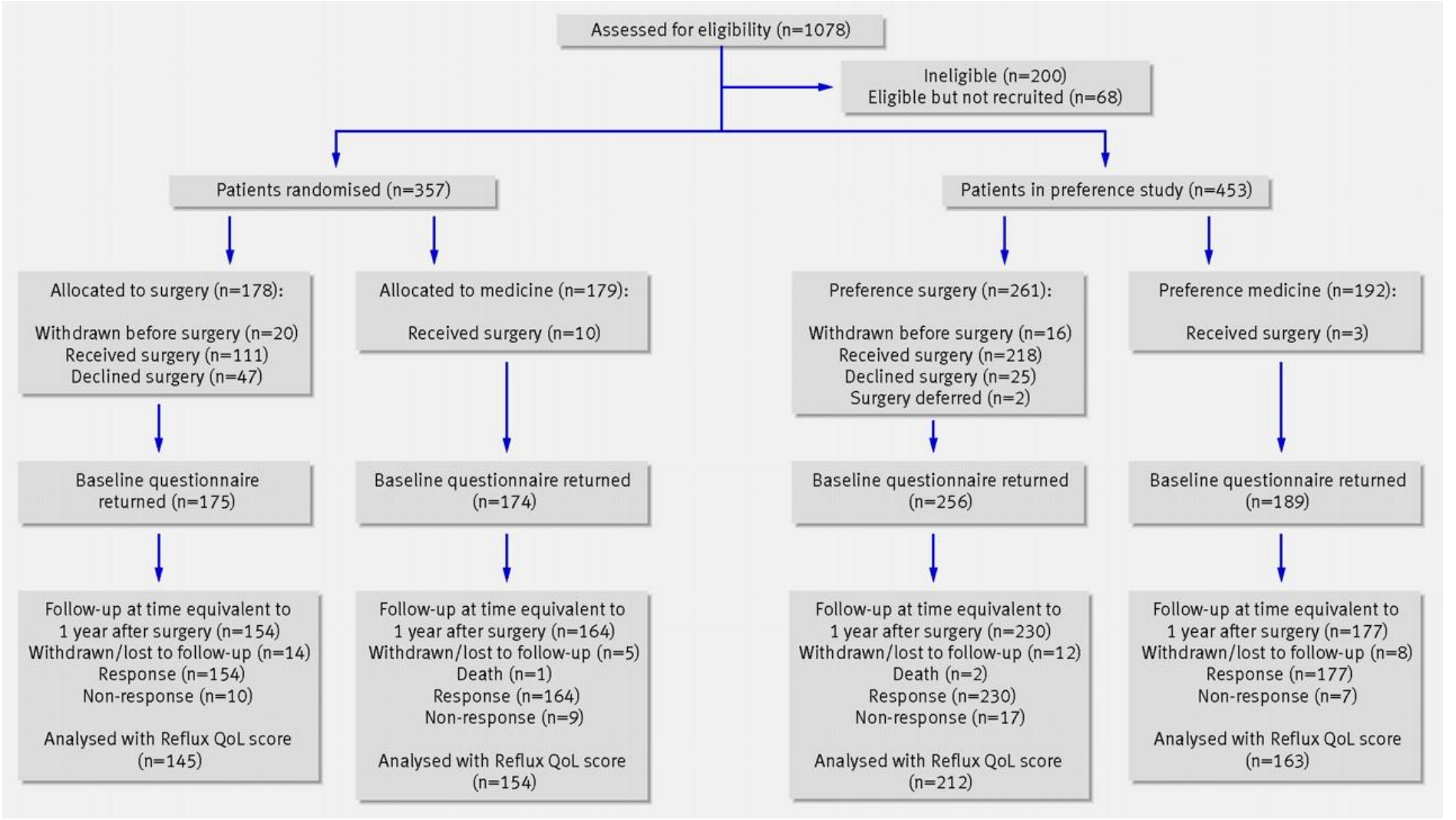


Fig. 2. Flow diagram of a multicentre trial of fractional flow reserve versus angiography for guiding percutaneous coronary intervention (PCI) (adapted from Tonino et al [313]). The diagram includes detailed information on the excluded participants.

Minimal access surgery compared with medical management for chronic gastro-oesophageal reflux disease: UK collaborative randomised trial



BMJ. 2008 Dec 15;337:a2664.

Results: Recruitment

- Dates defining the periods of recruitment and follow-up
- Example

  “Age-eligible participants were recruited … from February 1993 to September 1994 … Participants attended clinic visits at the time of randomisation (baseline) and at 6-month intervals for 3 years.”(Ann Intern Med. 2000;133:516-26)

Results: Outcome and estimation

- Item 17a - For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
- Examples

Table 5 | Example of reporting of summary results for each study group (binary outcomes).* (Adapted from table 2 of Mease et al[103])

Endpoint	Number (%)		Risk difference (95% CI)
	Etanercept (n=30)	Placebo (n=30)	
Primary endpoint			
Achieved PsARC at 12 weeks	26 (87)	7 (23)	63% (44 to 83)
Secondary endpoint			
Proportion of patients meeting ACR criteria:			
ACR20	22 (73)	4 (13)	60% (40 to 80)
ACR50	15 (50)	1 (3)	47% (28 to 66)
ACR70	4 (13)	0 (0)	13% (1 to 26)

*See also example for item 6a.
PsARC=psoriatic arthritis response criteria. ACR=American College of Rheumatology.

Table 6 | Example of reporting of summary results for each study group (continuous outcomes). (Adapted from table 3 of van Linschoten[234])

	Exercise therapy (n=65)		Control (n=66)		Adjusted difference* (95% CI) at 12 months
	Baseline (mean (SD))	12 months (mean (SD))	Baseline (mean (SD))	12 months (mean (SD))	
Function score (0-100)	64.4 (13.9)	83.2 (14.8)	65.9 (15.2)	79.8 (17.5)	4.52 (−0.73 to 9.76)
Pain at rest (0-100)	4.14 (2.3)	1.43 (2.2)	4.03 (2.3)	2.61 (2.9)	−1.29 (−2.16 to −0.42)
Pain on activity (0-100)	6.32 (2.2)	2.57 (2.9)	5.97 (2.3)	3.54 (3.38)	−1.19 (−2.22 to −0.16)

*Function score adjusted for baseline, age, and duration of symptoms.

Results: Outcome and estimation

- Item 17b - For binary outcomes, presentation of **both absolute and relative effect sizes** is recommended
- Example

  "The risk of oxygen dependence or death was reduced by 16% (95% CI 25% to 7%). The absolute difference was -6.3% (95% CI -9.9% to -2.7%); early administration to an estimated 16 babies would therefore prevent 1 baby dying or being long-term dependent on oxygen" (also see table 7).

Table 7 | Example of reporting both absolute and relative effect sizes. (Adapted from table 3 of The OSIRIS Collaborative Group[242])

	Percentage (No)			
Primary outcome	Early administration (n=1344)	Delayed selective administration (n=1346)	Risk ratio (95% CI)	Risk difference (95% CI)
Death or oxygen dependence at "expected date of delivery"	31.9 (429)	38.2 (514)	0.84 (0.75 to 0.93)	−6.3 (−9.9 to −2.7)

Discussion

- Item 20 - Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
- Item 21 - Generalisability (external validity, applicability) of the trial findings
- Item 22 - Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

Other Information

- Registration
  - ✓ Registration number and name of trial registry
- Protocol
  - ✓ Where the full trial protocol can be accessed, if available
- Funding
  - ✓ Sources of funding and other support (such as supply of drugs), role of funders

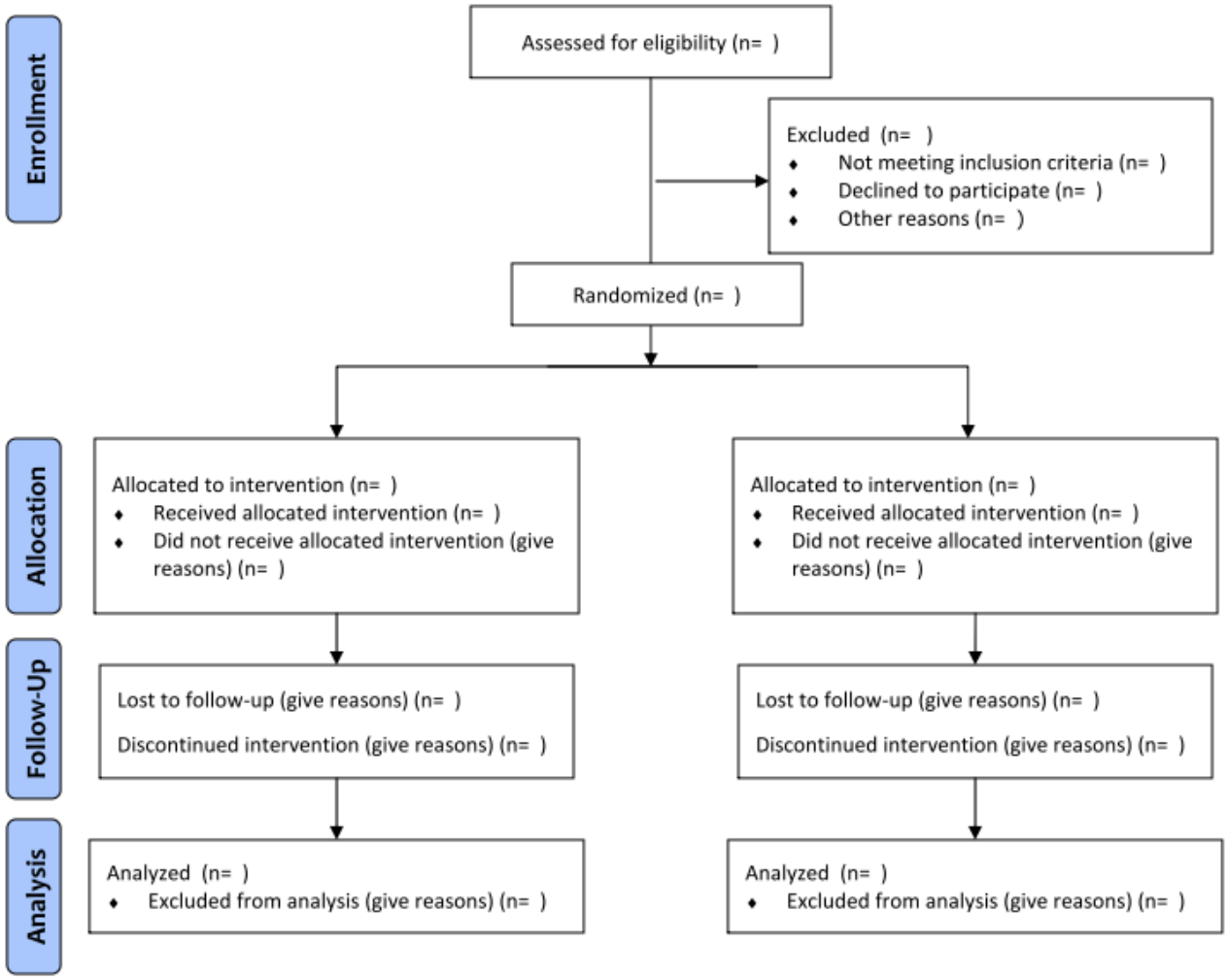
CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT Statement 2010 Flow Diagram



Extensions of the CONSORT Statement

The main CONSORT Statement is based on the "standard" two-group parallel design. However, there are several variations to the standard trial methodology, including different design aspects (e.g., cluster), interventions (e.g., herbals) and data (e.g., harms).

To help improve the reporting of these trials the main CONSORT Statement has been extended and modified by members of the CONSORT group for application in these various areas. The resulting CONSORT extensions are presented in this section. This list is, by no means, exhaustive; and work is constantly in progress.

Please note that modifications to the CONSORT checklist or flow diagram that are not developed with the involvement of the CONSORT Group do not have permission to name their work "CONSORT".

Some work, however, has been done to modify the CONSORT Statement without the involvement of the Group. These unofficial extensions of the CONSORT Statement can be found here.

Finding the Appropriate Extension

The table below lists the current official extensions of the CONSORT statement. You can click on each extension to learn more about it or to explore that extension in the checklist viewer application.

Designs	Interventions	Data
Cluster Trials	Herbal Medicinal Interventions	CONSORT-Pro
Non-Inferiority and Equivalence Trials	Non-Pharmacologic Treatment Interventions	Harms
Pragmatic Trials	Acupuncture Interventions	Abstracts

Impact of CONSORT

- More than 400 journals have endorsed CONSORT.
- **How to endorse the CONSORT Statement (Journal)**
  - ✓ Include mention of the CONSORT Statement and refer to the CONSORT web link (www.consort-statement.org) in the journal's instructions to authors for reporting of randomized trials, or in the organization's resource section.
  - ✓ Include an editorial in the journal to this effect along with the journal's policy on helping to improve the quality of reporting clinical trials.
  - ✓ Allow us to add your journal's name to its list of journal endorsers by contacting us.

WILEY-BLACKWELL
Journal of Gastroenterology and Hepatology JGHF

Registration of Clinical Trials

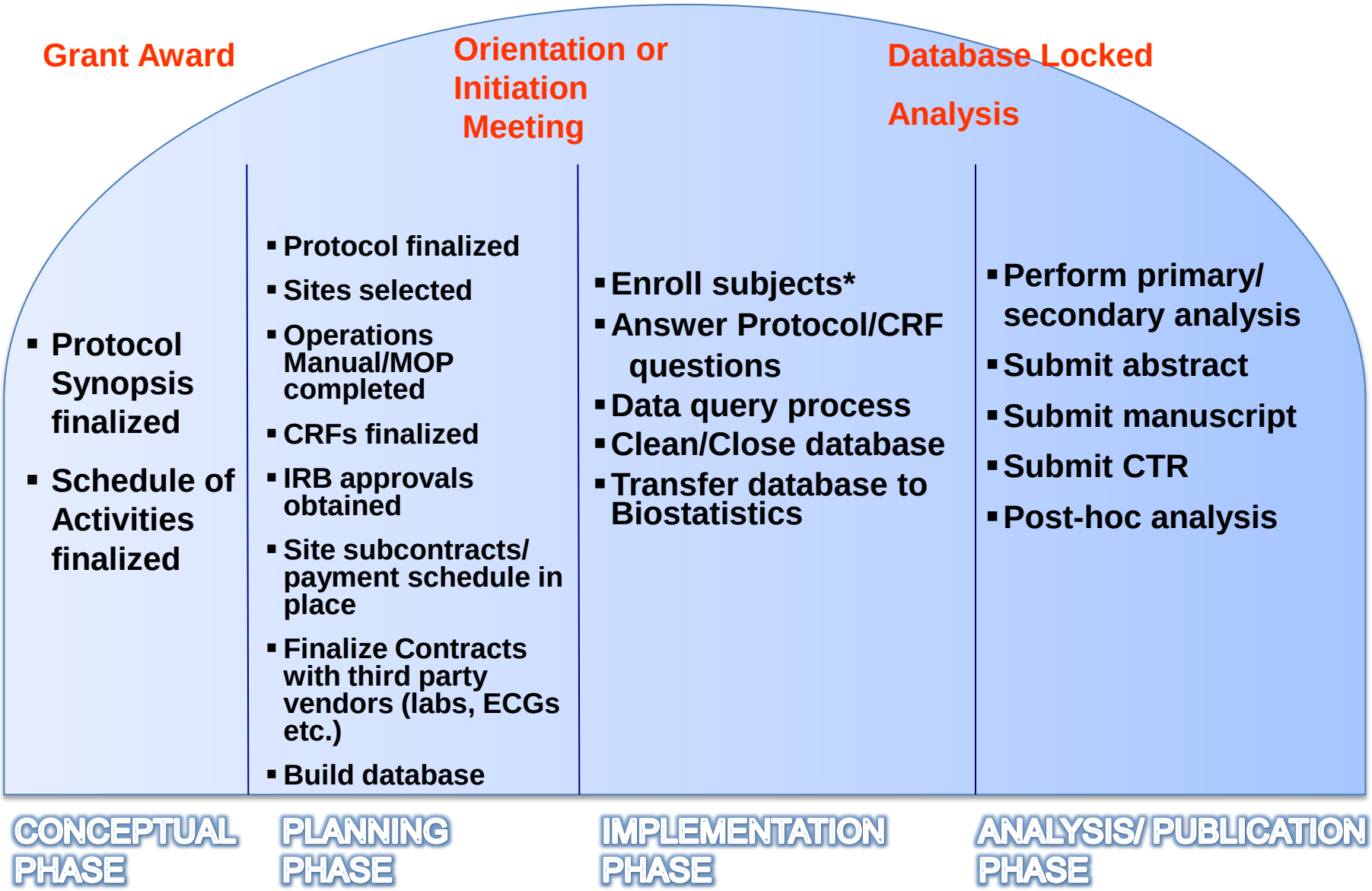
We strongly recommend, as a condition of consideration for publication, registration in a public trials registry. Trials register at or before the onset of patient enrolment. This policy applies to any clinical trial starting enrolment after July 1, 2008. For trials that began enrolment before this date, we request registration by December 1, 2008, before considering the trial for publication. We define a clinical trial as any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Studies designed for other purposes, such as to study pharmacokinetics or major toxicity (e.g., phase 1 trials) are exempt.
We do not advocate one particular registry, but registration with a registry that meets the following minimum criteria:
(1) accessible to the public at no charge;
(2) searchable by standard, electronic (Internet-based) methods;
(3) open to all prospective registrants free of charge or at minimal cost;
(4) validates registered information;
5) identifies trials with a unique number; and
(6) includes information on the investigator(s), research question or hypothesis, methodology, intervention and comparisons, eligibility criteria, primary and secondary outcomes measured, date of registration, anticipated or actual start date, anticipated or actual date of last follow-up, target number of subjects, status (anticipated, ongoing or closed) and funding source(s).

Registries that currently meet these criteria include, but are not limited to:
(1) the registry sponsored by the United States National Library of Medicine (www.clinicaltrials. gov);
(2) the International Standard Randomized Controlled Trial Number Registry (http://www.controlled-trials.com);
(3) the Australian Clinical Trials Registry (http://www.actr.org.au);
(4) the Chinese Clinical Trials Register (http://www.chictr.org); and
(5) the Clinical Trials Registry - India (http://www.ctri.in); (6) University hospital Medical Information Network (UMIN) (http://www.umin.ac.jp/ctr/).

Randomized Controlled Trials

Reporting of randomized controlled trials should follow the guidelines of The CONSORT Statement: http://www.consort-statement.org Any experiments involving animals must be demonstrated to be ethically acceptable and where relevant conform to international standards for animal usage in research. These include but are not limited to the NHMRC of Australia, NIH and European Union.

Life Cycle of a Clinical Research



“The whole of medicine depends on the transparent reporting of clinical trials”

Rennie D. CONSORT revised—improving the reporting of randomized trials. *JAMA* 2001;285:2006.

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