临床研究注册

北医三院临床流行病学研究中心
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Outlines

- 临床试验注册的定义与原因
- 临床试验注册的历史与现状
- 临床试验注册的类型
- 临床试验的注册
- 临床试验注册的检索

临床试验注册：定义

WHO版:临床试验注册是将试验的设计方案、组织实施和管理等相关信息按照国际公认的形式刊登在可公开访问的网站上。所有的注册网站均需按照WHO的标准进行管理。

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.

为什么要进行临床研究注册

科学意义

- 医学研究者可以在试验的起始阶段就能获得相关试验的重要信息，知道谁在做什么研究，方法如何，避免不必要的重复研究；完善研究的相关内容，确保临床试验的严谨性。

伦理学意义

- 促进试验的规范性；
- 病人志愿参加临床试验，承担了风险和成本，他们有权获得试验结果以及他们为人类健康事业的发展和医疗服务决策的制定所作出的贡献
- 赫尔辛基宣言规定，“在第一个主体募集前，每个临床试验都必须在可公开访问的数据库中注册”

为什么要进行临床研究注册

循证医学意义

- 有助于避免选择性发表偏倚，防止未报道阴性结果或结果不明确而误导研究人员作出有偏倚的系统综述，影响临床医疗决策

社会学意义

- 有助于社会公众增进对临床试验的了解，提高公众对临床疗效真实性的认识，有助于提高公众对药品/器械生产企业的信任度

强制性要求

- 法律法规要求； 文章发表要求。

为什么要进行临床研究注册

国际医学期刊编辑委员会（International Committee of Medical Journal Editors, ICMJE）要求所有临床试验在发表之前必须进行国际注册，否则不予发表试验结果。（2005.9）

临床试验注册的历史

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS 国际医学杂志编辑委员会

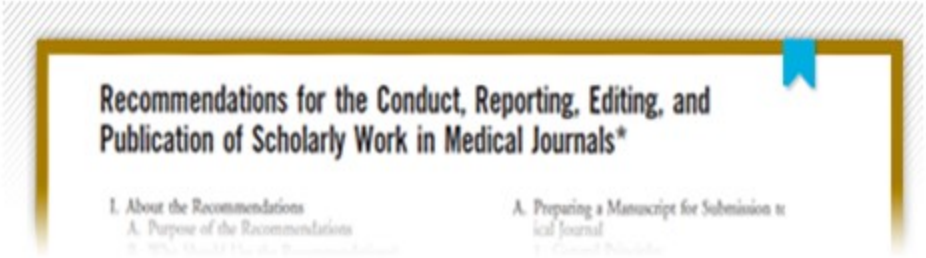
The ICMJE is a small group of general medical journal editors and representatives of selected related organizations working together to improve the quality of medical science and its reporting. ICMJE meets annually to refine its Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals.

临床试验注册的历史

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

国际医学杂志编辑委员会

Recommendations


Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*

I. About the Recommendations
A. Purpose of the Recommendations

A. Preparing a Manuscript for Submission to

Conflicts of Interest


ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

ICMJE Form for Disclosure of Potential Conflicts of Interest

世界卫生组织国际临床试验注册平台
WHO ICTRP

- 在2004年11月于墨西哥的墨西哥市召开的卫生研究部长峰会之后，与会者要求WHO促进“一个连接国际临床试验登记网络的平台，以确保一个单一的存取点和试验的明确识别”的建立。
- WHO ICTRP的主要目标就是促进所有临床试验WHO试验注册数据集的预期注册以及公众对该信息的可访问性。

- **WHO ICTRP不是临床试验注册中心**

Landmark

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

World Health Organization

国际医学杂志编辑委员会（ICMJE）、世界卫生组织以及国家政府组织

支持临床试验注册，要求临床试验在招募受试者之前将试验具体措施向公众开放，并以此作为允许试验结果发表的条件。

2004年9月，ICMJE

宣布从2005年7月1日起，只发表已在公共临床试验注册机构注册的临床试验结果报告。

2004年11月WHO

牵头建立国际临床试验注册平台(International Clinical Trials Registry Platform, ICTRP）；

为临床试验注册库制定标准

WHO为临床试验注册库制定了一系列标准

WHO一级注册机构

- WHO一级注册机构符合内容、质量和有效性、可访问性、唯一标识、技术能力和管理的具体标准。WHO一级注册机构满足ICMJE的要求。

  http://www.who.int/ictrp/network/primary/en/

中国临床试验注册中心 华西

http://www.chictr.org/cn/

目前已完成注册17991项

World Health Organization

Health topics

International Clinical Registry Platform
About
Registry Network
Search portal
Unambiguous trial id
Reporting of findings
News and events
Publications
Clinical trials in child

Primary Registries

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	Profile	Website
Japan Primary Registries Network (JPRN)	Profile	Website(in Japanese)
		Network members: UMIN CTR, JapicCTI, JMACCT CTR
Thai Clinical Trials Registry (TCTR)	Profile	Website
The Netherlands National Trial Register (NTR)	Profile	Website
Pan African Clinical Trial Registry (PACTR)	Profile	Website
Peruvian Clinical Trial Registry (REPEC)	Profile	Website
Sri Lanka Clinical Trials Registry (SLCTR)	Profile	Website

中国临床试验注册中心


ChiCTR 中国临床试验注册中心
Chinese Clinical Trial Registry
世界卫生组织国际临床试验注册平台一级注册机构
网站首页 | ChiCTR简介 | 检索入口 | 重要文件 | 注册指南 | 常见问题
http://www.chictr.org
访问网站
世界卫生组织国际临床试验注册平台一级注册机构
统计数据
已完成注册 21091
预注册 16686
补注册 4402
治疗性研究 11548
预防性研究 143
诊断试验 1019
病因学研究 350
预后研究 221
流行病学研究 339
相关因素研究 2008
观察性研究 4896
检索试验
按国家、省（市）统计
按疾病代码统计
按试验实施单位统计
按试验主办单位统计
按经费或物资来源统计
按征募研究对象情况统计
按注册状态统计
按干预措施统计
按伦理委员会统计
按研究类型统计

主要的国际临床试验注册库

1 Clinical Trials注册资料库（http://www.clinicaltrials.gov）

2 英国国立研究注册库（BNRR, http://www.nrr.nhs.uk）

3 澳大利亚临床试验注册库（ACTR,http://www.actr.org.au/）

4 英国当前对照试验注册库（CCT,http://www.controlled-trials.com）

5 Trials Central注册库（http://www.trialscentral.org/）

6 英国国际标准随机对照试验号注册库

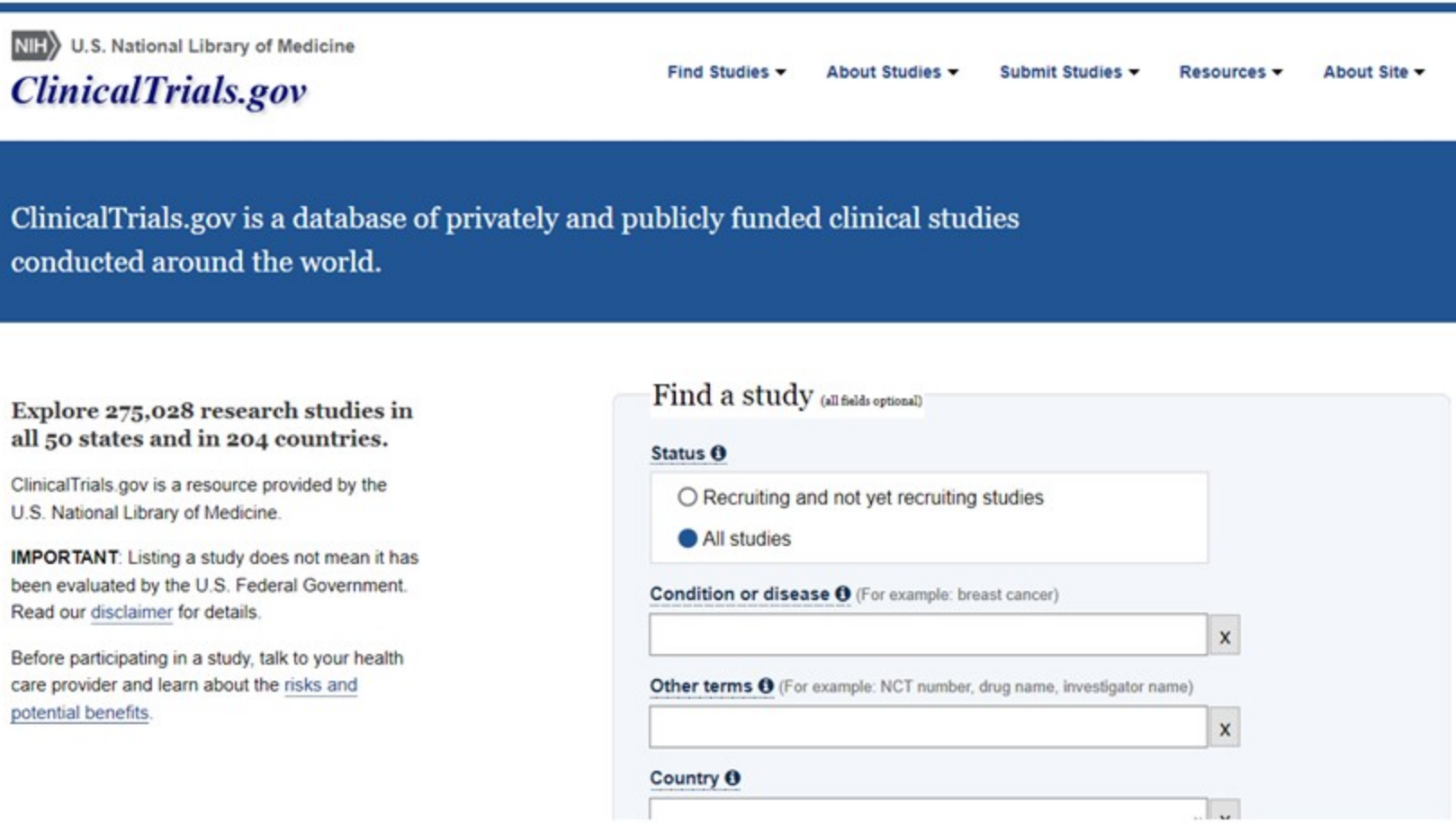
（ISRCTN,http://www.isrctn.org/）

- **Clinical Trials作为应用最广泛的注册库**

NIH临床试验注册平台

- http://www.clinicaltrials.gov/
- 美国临床试验注册平台面向全世界进行临床试验.
- 2007年，美国FDA（ FDAAA 801 ）要求要求所有临床试验进行注册，并在clinicaltrials.gov执行。
- 注册入口：Protocol Registration and Results System (PRS) *https://register.clinicaltrials.gov/*

NIH临床试验注册平台



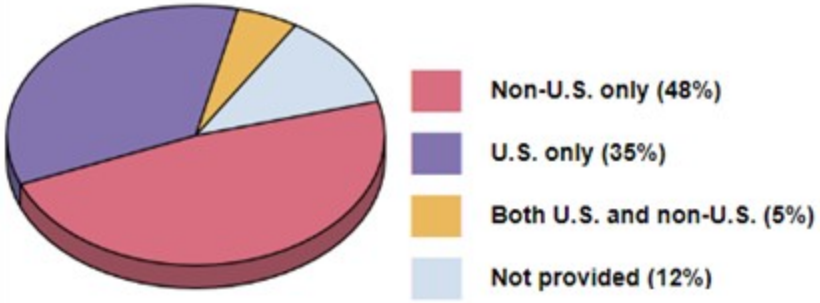
The table below shows the number and types of studies that are registered and have results posted on ClinicalTrials.gov.

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Study and Intervention Type (as of March 14, 2019)		Number of Registered Studies and Percentage of Total	Number of Studies With Posted Results and Percentage of Total***
Total		300,060	35,477
Interventional		237,782 (79%)	33,414 (94%)
Type of Intervention*	Drug or biologic	136,349	26,414
	Behavioral, other	75,005	6,051
	Surgical procedure	25,166	1,804
	Device**	29,932	4,258
Observational		60,935 (20%)	2,063 (6%)
Expanded Access		548	N/A

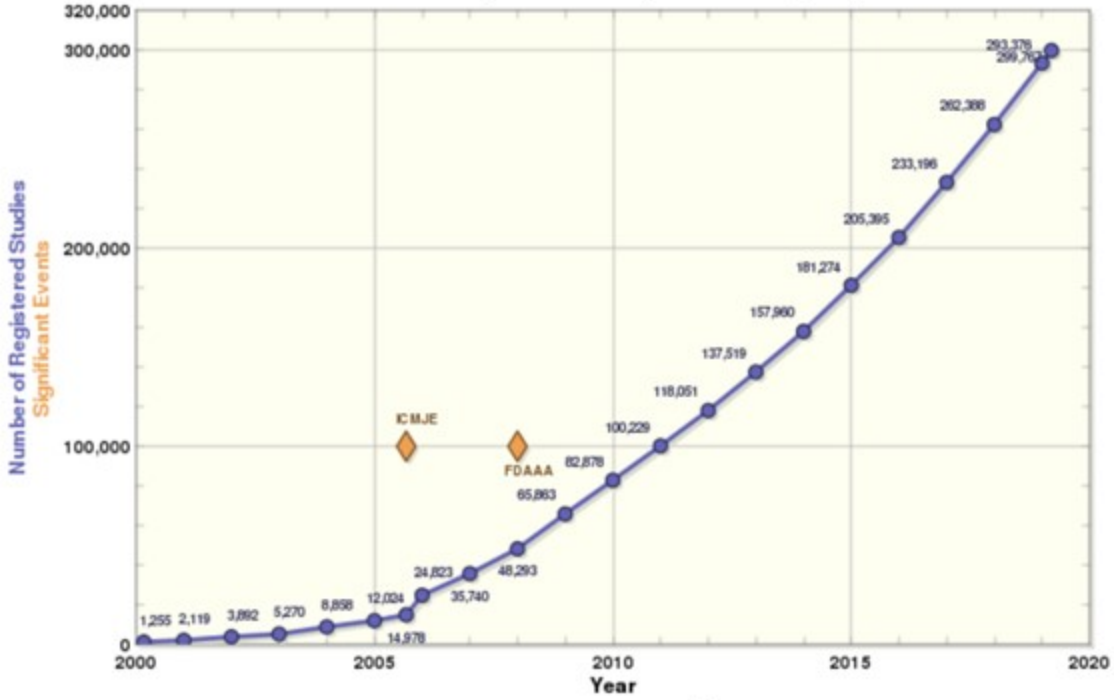
Percentage of Registered Studies by Location (as of February 26, 2019)

Total of 298,505 studies

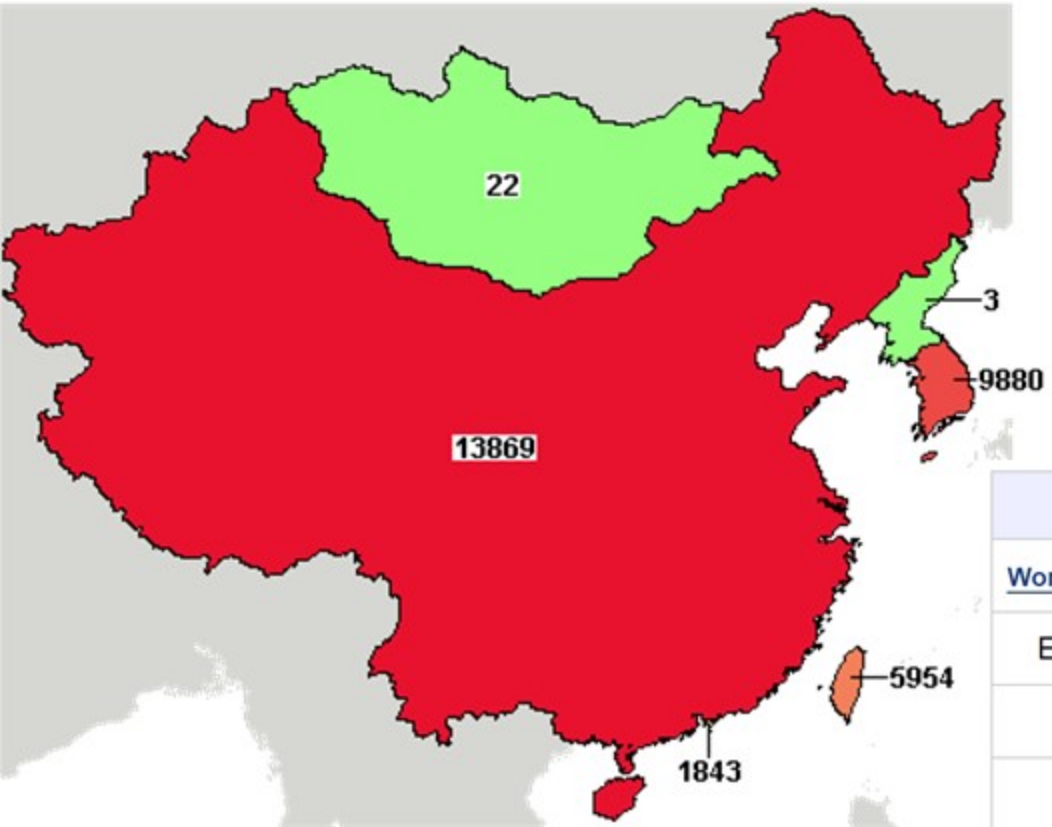


Location	Number of Registered Stu (as of Febru
Non-U.S. only	143,717 (48%)
U.S. only	103,196 (35%)
Both U.S. and non-U.S.	15,869 (5%)
Not provided	35,723 (12%)
Total	298,505 (100%)

Number of Registered Studies Over Time and Some Significant Events (as of March 14, 2019)



中国在NIH平台上注册现状



Region Name	Number of Studies
World	300,209
East Asia	32,595
China	13,869
Hong Kong	1,843
Korea, Democratic People's Republic of	3
Korea, Republic of	9,880
Mongolia	22
Taiwan	5,954

什么研究要进行研究注册

临床试验是指以人为对象的前瞻性研究，预先将受试者或受试人群分配至接受一种或多种医疗干预，以评价医疗干预对健康结局的影响。其中“医疗干预”包括但不仅限于药物、细胞及其他生物制品、外科治疗、放射治疗、医疗器械、行为疗法、治疗过程的改变、预防保健等。 其定义包括第1阶段到第4阶段的试验。

——WHO

什么研究要进行研究注册

A clinical trial is a research study in which human volunteers are assigned to interventions (for example, a medical product, behavior, or procedure) based on a protocol (or plan) and are then evaluated for effects on biomedical or health outcomes. ClinicalTrials.gov also includes records describing observational studies and programs providing access to investigational drugs outside of clinical trials (expanded access).

——clinicaltrials.gov

什么研究要进行研究注册

所有在人体中和采用取自人体的标本进行的研究，包括各种干预措施的疗效和安全性的有对照或无对照试验（如随机对照试验、病例-对照研究、队列研究及非对照研究）、预后研究、病因学研究、和包括各种诊断技术、试剂、设备的诊断性试验，均需注册并公告。

——chiCTR

“与人有关”

什么研究要进行研究注册

- ICMJE requires, and recommends that all medical journal editors require, registration of clinical trials in a public trials **registry at or before the time of first patient enrollment** as a condition of consideration for publication.
- ICMJE defines a clinical trial as any research project that prospectively assigns people or a group of people to an **intervention**, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a **health-related intervention** and **a health outcome**.

——ICMJE

The table below shows the number and types of studies that are registered and have results posted on ClinicalTrials.gov.

Study and Intervention Type (as of March 14, 2019)		Number of Registered Studies and Percentage of Total	Number of Studies With Posted Results and Percentage of Total***
Total		300,060	[illegible]
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Type of Intervention*	Drug or biologic	136,349	
	Behavioral, other	75,005	
	Surgical procedure	25,166	
	Device**	29,932	
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Expanded Access		548	

统计数据

已完成注册 21091
预注册 16686
补注册 4402
治疗性研究 11548
预防性研究 143
诊断试验 1019
病因学研究 350
预后研究 221
流行病学研究 339
相关因素研究 2008
观察性研究 4896

怎样注册

- 华西中心，双语注册。在完成中、英文注册资料的上传后两周内获得注册号（UTN识别码），获得注册号后第二周可在WHO ICTRP可检索到已注册试验。

- NIH临床试验注册平台，英语注册。试验方案注册系统（PRS），获得临床试验注册号（NCT），至此，该试验方案才得以成功注册。通过NCT，任何人都可以通过网络直接链接到该试验。Pubmed可查询。（速度较快）

中国临床试验如何注册？

注册指南

请仔细阅读本指南，如有疑问，请与我们联系（推荐使用电子邮件或QQ）：

官方电子邮件： 1193142709@qq.com; chictr@hotmail.com; chictr@edu.scu.cn; 617767@qq.com

QQ: 1193142709

Skype: wutaixiang

电话: 18980604562

请注意：

为了适应注册量快速增加的需要，我们对网站进行了更新，完成了对网站的升级并采用顶级域名：www.chictr.org.cn，每周上传世界卫生组织ICTRP。

所有新注册试验均在新网址www.chictr.org.cn进行，原网址不再进行新的试验注册。

请所有注册均转到新网址www.chictr.org.cn进行。

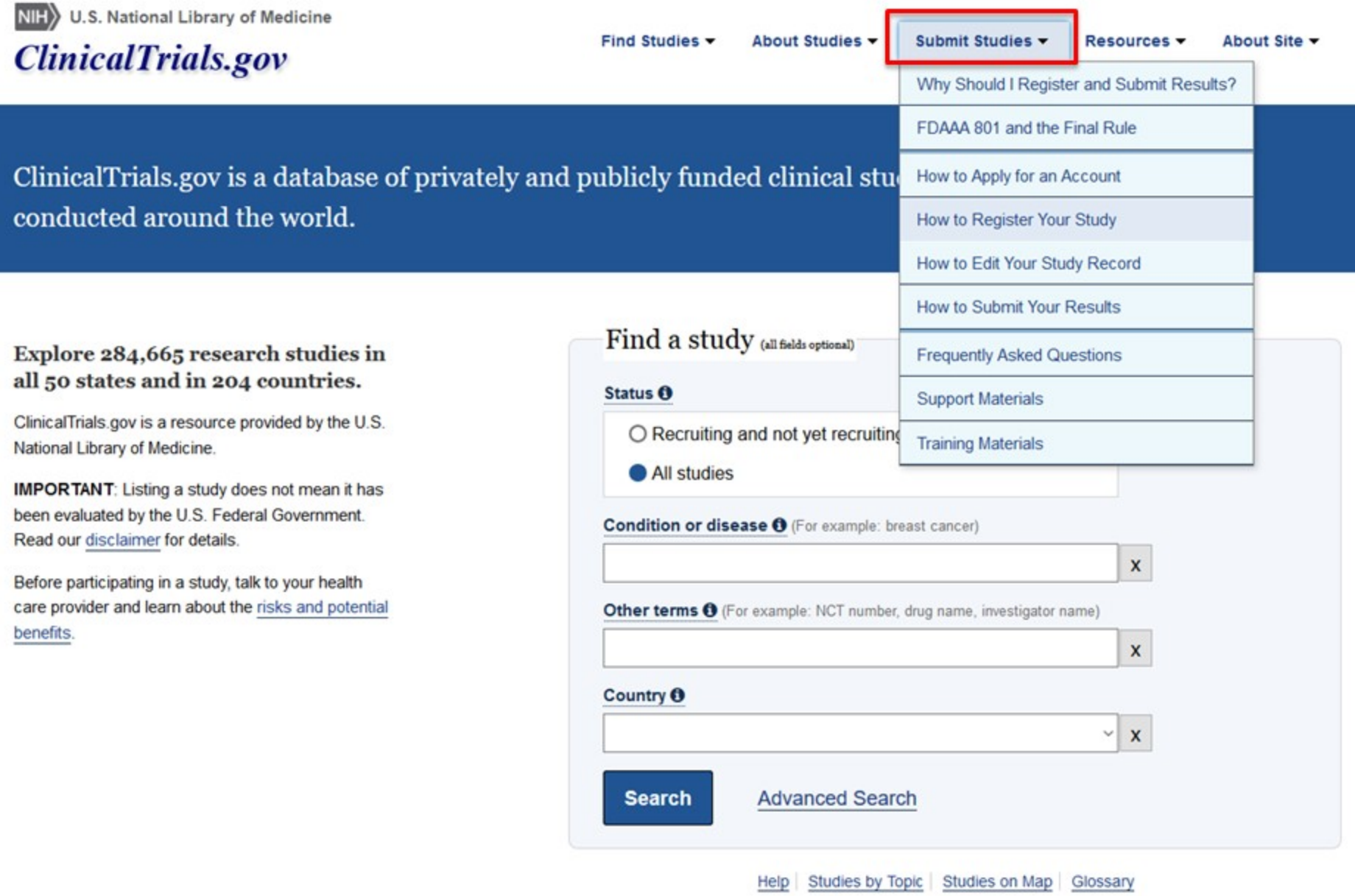
中国临床试验如何注册？

中、英文双语注册

凡在中国大陆和台湾实施的临床试验均需采用中、英文双语注册。来自于香港特别行政区和其他国家实施的临床试验可只采用英语注册。

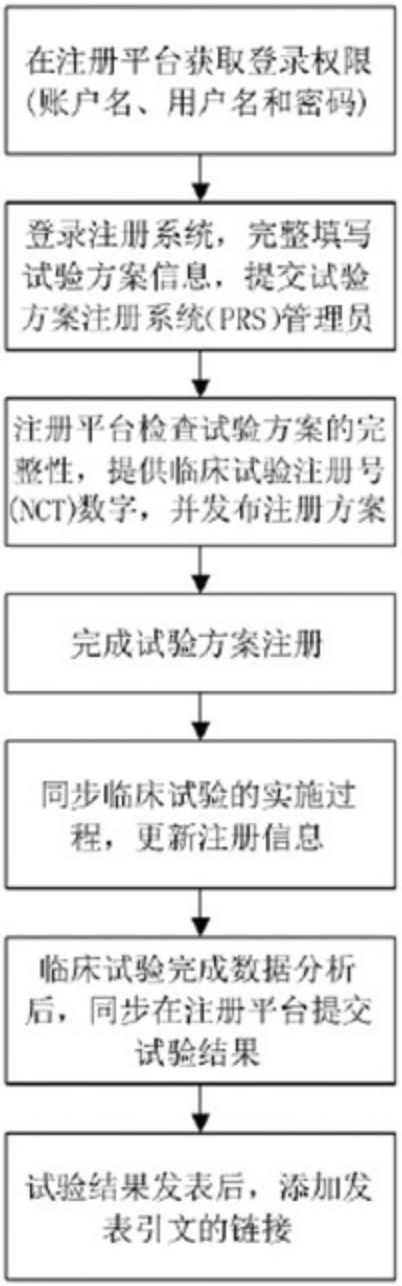
在完成中、英文注册资料的上传后两周内可获得注册号，获得注册号后一周内（特殊情况除外）可在世界卫生组织国际临床试验注册平台检索入口(WHO ICTRP search portal)检索到已注册试验。

临床试验注册的内容(WHO)


NIH U.S. National Library of Medicine
ClinicalTrials.gov
Find Studies
About Studies
Submit Studies
Resources
About Site
Why Should I Register and Submit Results?
FDAAA 801 and the Final Rule
How to Apply for an Account
How to Register Your Study
How to Edit Your Study Record
How to Submit Your Results
Frequently Asked Questions
Support Materials
Training Materials
ClinicalTrials.gov is a database of privately and publicly funded clinical stu
conducted around the world.
Explore 284,665 research studies in all 50 states and in 204 countries.
ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.
IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.
Before participating in a study, talk to your health care provider and learn about the risks and potential benefits.
Find a study (all fields optional)
Status
Recruiting and not yet recruiting
All studies
Condition or disease (For example: breast cancer)
Other terms (For example: NCT number, drug name, investigator name)
Country
Search
Advanced Search
Help
Studies by Topic
Studies on Map
Glossary

临床试验注册基本流程

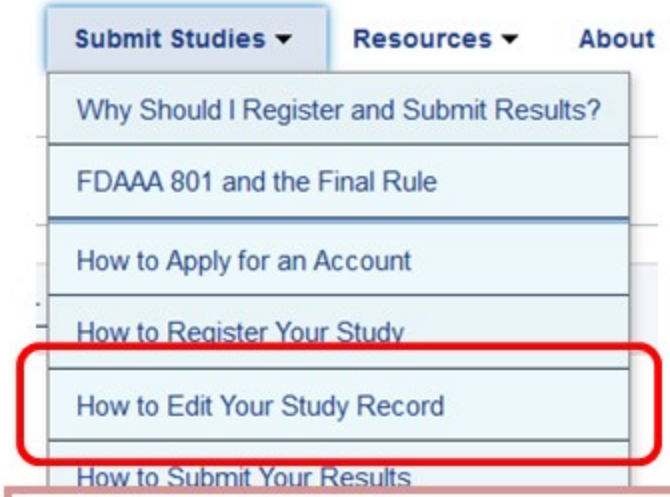
clinicaltrials.gov



临床试验注册要提交的内容

- 项目负责人、funding、研究目的、研究内容、纳入及排除标准、多中心研究中各中心需纳入受试者数量、中心的地点和联系方式、研究终点与观察指标、技术路线、分组及随机化方法、统计方法、知情同意书、伦理委员会批件、研究开始和结束时间等等。

修改方案需要更新注册内容（clinicaltrials.gov为例）



Editing and Updating a Record

At any time, you can make updates and edits to a record published on ClinicalTrials.gov by logging into the Protocol Registration and Results System (PRS) and clicking on **Edit Record** under the Protocol Records heading on the PRS main menu. After you finish making changes, you will need to release (submit) the record to ClinicalTrials.gov for review and processing. See the ClinicalTrials.gov protocol review criteria (PDF) for a description of items that should be addressed before releasing the record to ClinicalTrials.gov. See the ClinicalTrials.gov Protocol Information Review Process for more information.

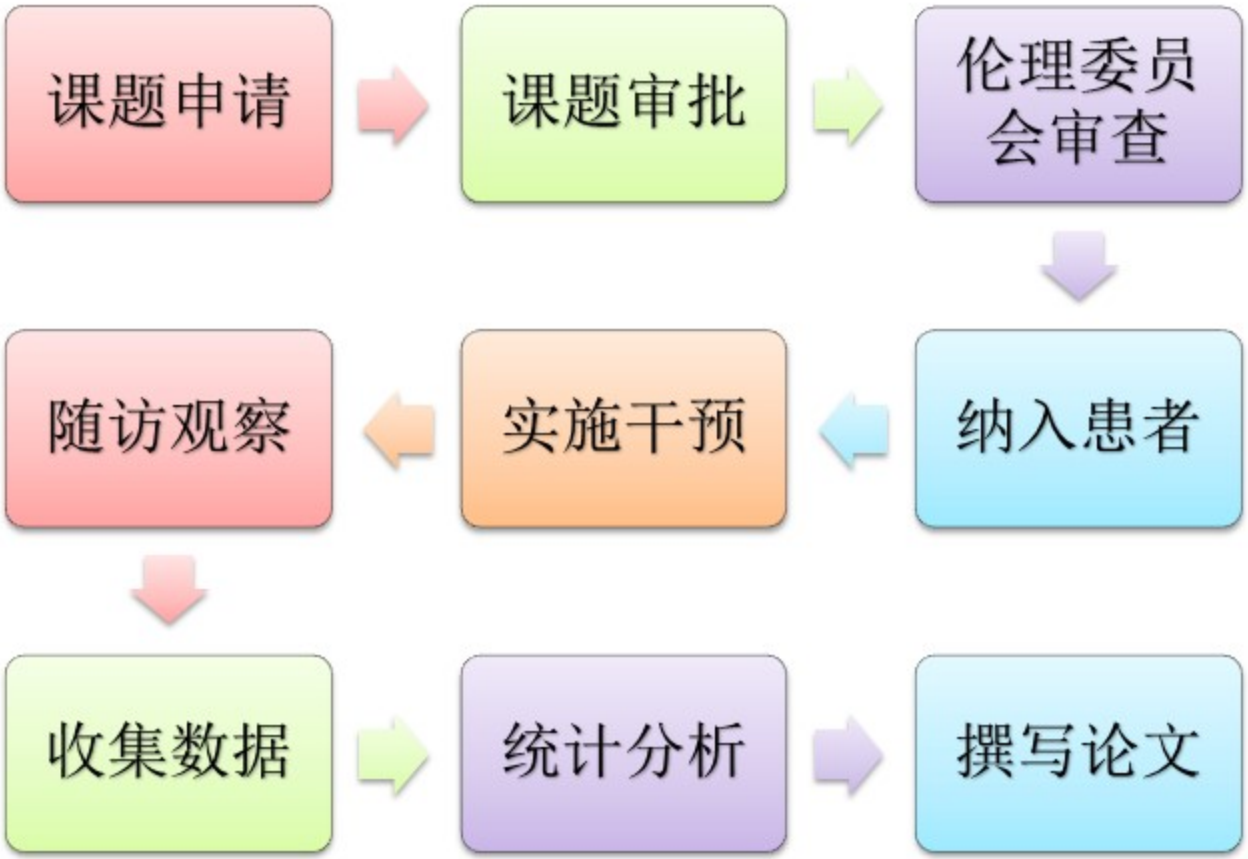
注册信息的更新

- 纳入第一例受试者后更新研究实际开始时间（30天内）
- 纳入最后一例受试者后更新入组完成时间（30天内）
- 完成所有人随访后更新研究完成时间（30天内）

提交试验结果

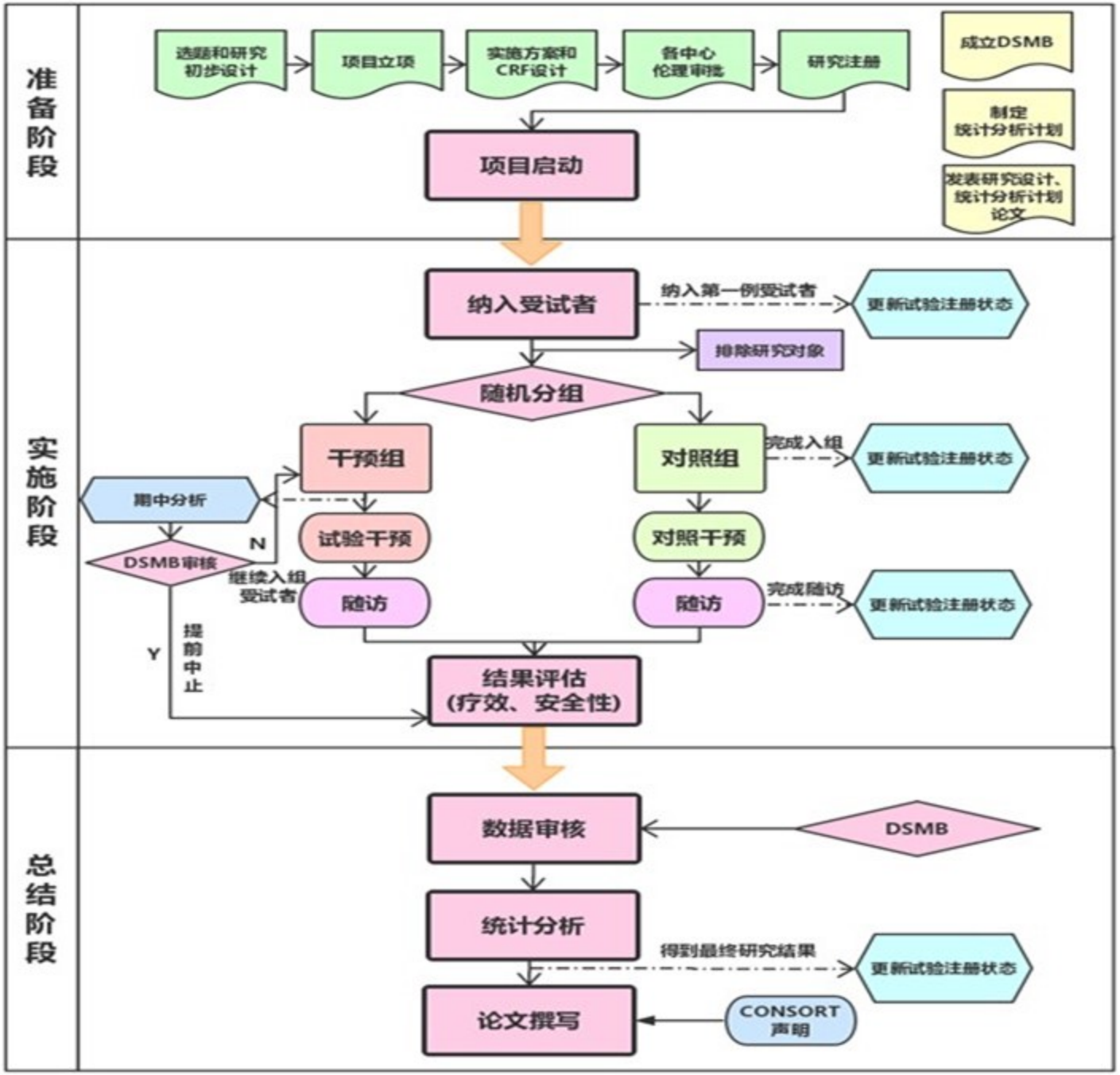
- 试验完成**一年内**更新主要的统计分析结果。

临床研究流程的影响



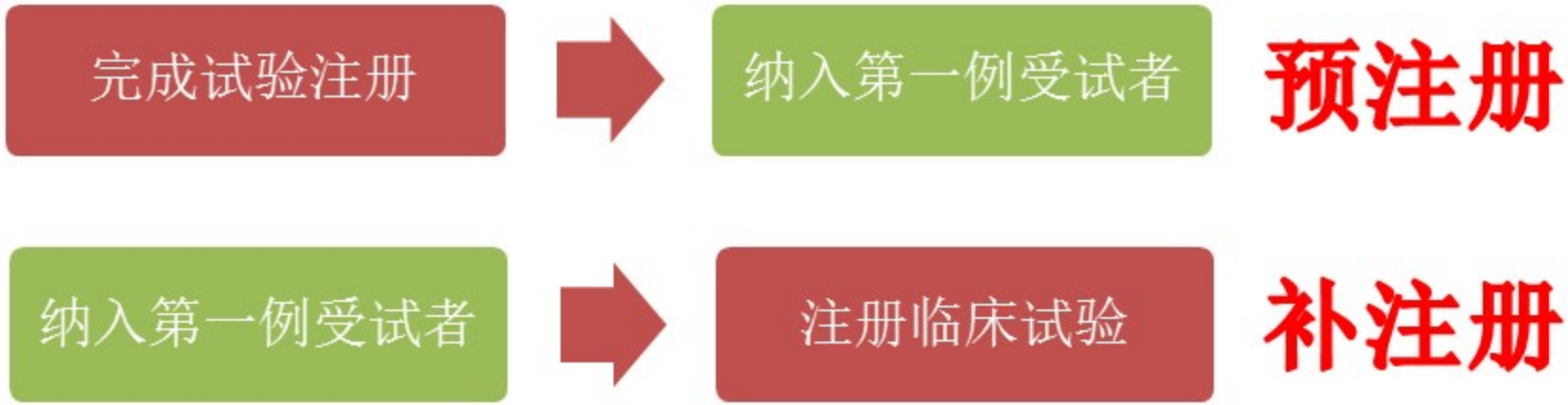
临床研究流程的影响


课题申请
课题审批
伦理委员会审查
试验注册
纳入患者
实施干预
上报截止入组时间
随访观察
上报截止随访时间
收集数据
统计分析
撰写论文
研究结果上传


准备阶段
选题和研究初步设计
项目立项
实施方案和CRF设计
各中心伦理审批
研究注册
项目启动
成立DSMB
制定统计分析计划
发表研究设计、统计分析计划论文
实施阶段
纳入受试者
纳入第一例受试者
更新试验注册状态
排除研究对象
随机分组
干预组
对照组
完成入组
更新试验注册状态
期中分析
试验干预
对照干预
N
DSMB审核
继续入组受试者
随访
随访
完成随访
更新试验注册状态
Y
提前中止
结果评估(疗效、安全性)
总结阶段
数据审核
DSMB
统计分析
得到最终研究结果
更新试验注册状态
论文撰写
CONSORT声明

预注册 VS 补注册

- 《赫尔辛基宣言v.08》要求任何临床试验必须在纳入第一例受试者之前在公共注册机构注册。



预注册

免费
研究完成1年内提交统计结果

补注册

- 付费（3k）
- 提交研究结果的原始数据
- 临床试验数据库公共管理平台ResMan

临床研究注册的检索


今天是：2019-02-28 星期四
ChiCTR 中国临床试验注册中心
Chinese Clinical Trial Registry
世界卫生组织国际临床试验注册平台一级注册机构
网站首页 | ChiCTR简介 | 检索入口 | 重要文件 | 注册指南 | 常见问题
简体中文 | English
检索试验
按国家、省（市）统计
按疾病代码统计
按试验实施单位统计
按试验主办单位统计
按经费或物资来源统计
按征募研究对象情况统计
按注册状态统计
按干预措施统计
按伦理委员会统计
按研究类型统计
检索试验
项目筛选条件
注册题目
阿司匹林
正式科学名
研究课题代号(代码)
注册状态
不限
注册号
在其它机构的注册号
筛选结果
更多筛选
共检索到38个符合检索条件的试验。
历史版本
注册号
注册题目
研究类型
注册时间
历史版本
ChiCTR1900020944
一项在健康中国受试者中比较餐后状态下给予含氯吡格雷和肠溶阿司匹林的复方片剂与同时给予这两种药物单方制剂的开放、随机、两种制剂、三周期、三序列、交叉生物等效性研究
首都医科大学附属北京世纪坛医院
干预性研究
2019/01/22
历史版本
ChiCTR1800020377
阿司匹林用于烟雾病人群的疗效研究
首都医科大学附属北京天坛医院
观察性研究
2018/12/27
版本
ChiCTR1800020289
人工关节置换术后使用阿司匹林vs使用利伐沙班进行静脉血栓栓塞预防的随机对照研究
干预性研究
2018/12/22

Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About Site ▾

Home > Search Results

Modify Search Start Over

1846 Studies found for: **aspirin**

Also searched for **Acetylsalicylic Acid** and **Arthritis Pain**. See Search Details

List | By Topic | On Map | Search Details

Show Filters

Download Subscribe to RSS

Showing: 1-10 of **1,846** studies 10 studies per page

Show/Hide Columns

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	☐	Not yet recruiting	Serum Thromboxane B2 Assay as a Measure of Platelet Production in Healthy Volunteers Taking **Aspirin**	• **Aspirin**	• Drug: **Aspirin** 81 mg	
2	☐	Active, not recruiting	Effect of Preoperative **Aspirin** in Patients Undergoing Off-pump Coronary Artery Bypass Grafting	• Coronary Artery Disease • **Aspirin**	• Drug: **Aspirin** • Drug: vitamin C	• Medinet Heart Centre Nowa Sol, Lubuskie, Poland
3	☐	Active, not recruiting	**Aspirin** Supplementation for Pregnancy Indicated Risk Reduction In Nulliparas (**ASPIRIN**)	• Premature Birth	• Drug: Low dose **aspirin** • Drug: Placebo	• University of Alabama, Birmingham Birmingham, Alabama, United States • University of Colorado, Denver Denver, Colorado, United States

临床试验注册的检索

International Clinical Trials Registry Platform (ICTRP)

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.

WHO/P. Virot

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

http://apps.who.int/trialsearch/

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

☐ Search for clinical trials in children

☐ Without Synonyms

Phases are: All, Phase 0, Phase 1, Phase 2, Phase 3, Phase 4

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
- 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 now enabled)
- A new field called 'Prospective registration' has been added to the ICTRP database, More details about this new field can be found here

Data Providers

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

- Australian New Zealand Clinical Trials Registry, last data file imported on **10 September 2018**
- Chinese Clinical Trial Registry, last data file imported on **10 September 2018**
- ClinicalTrials.gov, last data file imported on **10 September 2018**
- EU Clinical Trials Register (EU-CTR), last data file imported on **10 September 2018**
- ISRCTN, last data file imported on **10 September 2018**
- The Netherlands National Trial Register, last data file imported on **10 September 2018**

Every 4 weeks:

- Brazilian Clinical Trials Registry (ReBec), last data file imported on **10 September 2018**
- Clinical Trials Registry - India, last data file imported on **11 September 2018**
- Clinical Research Information Service - Republic of Korea, last data file imported on **11 September 2018**
- Cuban Public Registry of Clinical Trials, last data file imported on **27 August 2018**
- German Clinical Trials Register, last data file imported on **27 August 2018**
- Iranian Registry of Clinical Trials, last data file imported on **11 September 2018**
- Japan Primary Registries Network, last data file imported on **10 September 2018**
- Pan African Clinical Trial Registry, last data file imported on **10 September 2018**

World Health Organization

International Clinical Trials Registry Platform
Search Portal

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

Back to Search | Export to CSV | Export results to XML

3255 records for 2705 trials found for: aspirin (What is this?)

Show 10 records per page

Display synonyms

1 2 3 4 5 6 7 8 9 10 ... >>

Recruitment status	Prospective Registration	Main ID	Public Title	Date of Registration	Results available
Not Recruiting	Yes	CTRI/2018/09/015635	checking the difference between the drugs Fentanyl and Dexmedetomidine by giving in spinal canal by adding to Bupivacaine heavy in lower Limb orthopedic surgery	06-09-2018	
Not recruiting	Yes	NCT03661411	Antiplatelet vs R-tPA for Acute Mild Ischemic Stroke	05/09/2018	
Not Recruiting	Yes	CTRI/2018/09/015585	To study the effects of pregabalin on haemodynamics during laryngoscopic trachael intubation in patients with controlled hyprtension	05-09-2018	
Not Recruiting	No	CTRI/2018/09/015574	Comparison of insertion techniques of air-Q intubating laryngeal airway by fiberoptic bronchoscopic assessment in paediatric patients	04-09-2018	
Recruiting	Yes	NCT03661489	Efficacy and Safety of Remimazolam (CNS7056) Compared to Propofol for Intravenous Anesthesia During Elective Surgery	03/09/2018	
Not Recruiting	No	JPRN-UMIN000033984	Preventive effect of ecabet sodium on low-dose aspirin-induced small intestinal mucosal injury: A randomized, double-blind, pilot study	01/09/2018	
Not Recruiting	Yes	SLCTR/2018/029	Filgotinib in the Induction and Maintenance of Remission in Adults With Moderately to Severely Active Crohn's Disease (Diversity1)	2018-08-31	
Not Recruiting	Yes	CTRI/2018/08/015535	Observe effect of Dexmeditomidine drug to control vomitting after ear operation.	30-08-2018	
Not Recruiting	Yes	CTRI/2018/08/015513	Comparison of effects of two different doses of a drug in controlling responses to putting tube into windpipe	28-08-2018	
Not recruiting	No	ACTRN12618001451291	Comparison of remifentanil and alfentanil efficacy in sedation for colonoscopy	28/08/2018	

1 2 3 4 5 6 7 8 9 10 ... >>

为了进一步增加研究透明度……

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Editorials

Data sharing statements for clinical trials

BMJ 2017 ;: Editorial

Cite this as: E June 5, 2017

ONLINE FIRST FREE

Data Sharing Statements for Clinical Trials

A Requirement of the International Committee of Medical Journal Editors

Darren B. Taichman, MD, PhD[1]; Peush Sahni, MB, BS, MS, PhD[2]; Anja Pinborg, MD[3]; et al

Author Affiliations | Article Information

JAMA. Published online June 5, 2017. doi:10.1001/jama.2017.6514

Darren B Taichman et al.Data Sharing Statements for ClinicalTrials： A Requirement of the International Committee of Medical JournalEditors. NEJM, Lancet, BMJ, et al. 2017.6.

2018年7月及以后的临床试验报告，必须含数据共享声明

2019年1月1日后开始入组的临床试验，必须在临床试验注册平台上提交数据共享计划。

- 是否共享研究对象的个体数据
- 会共享哪些数据
- 研究相关的文档是否共享
- 数据将什么时间可获取以及可开放获取多长时间
- 对共享试验数据的入选要求

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

	Example 1	Example 2	Example 3	Example 4
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 (*Link to be included*).	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 (*Link to be included*).	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 (*Link to be included*).	Not applicable

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

谢 谢！

曾 琳

北京大学第三医院

临床流行病学研究中心

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