北京大学科研伦理与科研诚信培训第十九期（模块 A）日程

2018 年 9 月 20 日（星期四），时间：下午 01:00 - 04:30

地点：北京大学医学部逸夫教学楼 502

12:40 - 01:00	签到	
01:00 - 02:00	隐私保护：美国 HIPAA 法案的启示	王燕芳
02:00 - 03:00	临床研究注册：注意事项及经验分享	曾琳
03:00 - 03:10	休息	
03:10 - 04:10	欧盟一般数据保护法案（GDPR）的伦理启示	刘瑞爽
04:10 - 04:30	问题与讨论	

The HIPAA Privacy Rule

&

Clinical Research

王燕芳
北京大学临床研究所

CONTENTS 目录

1. What is HIPAA?
2. What was HIPAA created?
3. Whyat dose HIPAA consist of ?
4. Why should I care?
5. Effect on clinical research
6. Implementation at UMHS
7. Private rule & DICOM data transfer

01 What is HIPAA

Introduction

HIPAA：Health Insurance Portability and Accountability Act of 1996（健康保险流通与责任法案, 1996）

HIPAA是由美国国会颁布的联邦法律，并于1996年由总统签署

作为HIPAA法律的一部分，国会指示美国卫生和人类服务部（DHHS）制定法规，以便：
保护患者隐私，
保护以电子方式存储和传输的健康信息的安全性
最终的HIPAA隐私规则于2003年4月生效
最终的HIPAA安全规则于2005年4月生效

HIPAA compliance is <u>mandatory</u>

What is HIPAA？

- **H**ealth
- **I**nsurance
- **P**ortability and
- **A**ccountability
- **A**ct

02 WHY WAS HIPAA CREATED?

WHY WAS HIPAA CREATED?

- In 2000, many patients that were newly diagnosed with depression received free samples of anti-depressant medications in their mail.

- This left patients wondering how the pharmaceutical companies were notified of <u>their disease.</u>

- After a long and thorough investigation, the Physician, the Pharmaceutical company and a well-known pharmacy chain were all indicted on breach of confidentiality charges.

- This is one of the many reasons the Federal Government needed to step in and create guidelines to protect patient privacy.

03 What does HIPAA consist of?

What does HIPAA consist of?

1. Standardized Electronic Data Interchange **transactions** and codes for all covered entities.

2. Standards for **security** of data systems.

3. **Privacy** protections for individual health information.

4. Standard national **identifiers** for health care.

Important HIPAA definitions

- **Privacy** - state of being concealed; secret
- **Confidentiality** – containing private information (Ex. Medical Record).
- **Authorization** – to give permission for; to grant power to.
- **Breach Confidentiality** – to break an agreement, to violate a promise.
- **Disclosure** – means the release, transfer, provision of access to, or divulging of information outside the entity holding the information.
- **Use** – means the sharing, employment, application, utilization, examination, or analysis of individually identifiable information within an entity.

Important HIPAA terminology:
Protected Health Information

Protected Health Information [PHI] – is information that is created or received by a covered entity that:

- Relates to the past, present, or future physical or mental health of an individual.
- Identifies the individual or contains reasonable information that can be used to identify the individual(s).
- Examples of Protected Health Information:
  - Name, address, telephone, fax, email, social security number, medical diagnoses, medical records, account numbers and photographs or images.

Important HIPAA Terminology:
Notice of Privacy Practice

- Notice of Privacy Practice [NPP]- a notice given to patients concerning the use and disclosure of their Protected Health Information [PHI]

GENERAL RULES
Notice of Privacy Practices

- ◆ Health care providers and health plans will give out a Notice of Privacy Practices (NPP) that describes how we use and share their PHI, patients' rights regarding PHI, our responsibilities regarding PHI, and who to contact for more information.
- ◆ Click [here] to review our NPP.

What are a patient's rights under HIPAA

- Right to written Notice of Privacy Practices [NPP] that informs consumers how Protected Health Information [PHI] will be used and to whom it is disclosed
- Right of timely access to see and copy records for a reasonable fee
- Right to an amendment of records
- Right to restrict access and use
- Right to an accounting of disclosures
- Right to revoke authorization

REGULATIONS THAT PROTECT THESE RIGHTS?
THE JOINT COMMISSION STANDARDS

- Patient's rights:
  - Patients have a right to confidentiality of all information that is provided to the healthcare professional and institution.
  - Health care professionals ensure that patient information is secured at all times and if there are any complaints, those complaints will be resolved in a timely manner.

WHAT ARE THE HIPAA RULES AND REGULATIONS THAT PROTECT THESE RIGHTS?

RESEARCH ACTIVITIES

- **NO ONE** is permitted to use Protected Health Information for research without complying with the new HIPAA requirements.

- These HIPAA requirements are entirely separate from the existing federal human subject research regulations.

  - The Privacy Policies and Procedures do not replace or override other rules or procedures established by the Institutional Review Board [IRB], both must be complied with in order to conduct human research.

04 Why should I care

Why Should I Care?

- **The Health Insurance Portability and Accountability Act (HIPAA) is a federal law designed to improve the efficiency and effectiveness of the health care system.**

- **Part of HIPAA directly affects your clinical work and the operations of any facility where you will train.**

- **Understanding the fundamentals of HIPAA will prepare you to step into training sites with a clear understanding of how to comply with requirements for respecting the privacy of protected health information (PHI).**

OUR COMMITMENT TO PRIVACY

◆ The **University of Michigan** is committed to protecting the privacy and integrity of our patients' health information. The HIPAA Privacy Rule recognizes the importance and value of this commitment.

◆ This session will help us continue to do our part in protecting privacy.

Consequences of Violations

Inappropriate disclosure of confidential information is subject to discipline, up to and including discharge from employment. For licensed professionals, it is also subject to discipline by licensing and credentialing bodies

There are civil and criminal penalties for violations of patient privacy:

- Fines up to $25,000 for multiple violations of the same standard in a calendar year
- Fines up to $250,000 and/or imprisonment up to 10 years for deliberate misuses of individually identifiable health information.

Types of Data Protected by HIPAA

- Written documentation and all paper records
- Spoken and verbal information including voice mail messages
- Electronic databases and any electronic information, including research information, containing PHI stored on a computer, smart phone, memory card, USB drive, or other electronic device
- Photographic images
- Audio and Video recordings

The Privacy Rule applies to protected health information (PHI)

Protected health information (PHI) is "identifiable" health information acquired in the course of serving patients.

1. Name
2. Social security number
3. Street and email addresses
4. Employer
5. Telephone and fax numbers
6. Member or account numbers (e.g. medical record number, health plan identification number)
7. Relatives' names
8. Date of service, birth or death
9. Fingerprints, photographs, voice recordings
10. Certificate or license numbers
11. Any other linked number, code, characteristic (e.g. device identifiers, serial numbers)

To De-Identify Patient Information You Must Remove All 18 Identifiers

1. Names
2. Geographic subdivisions smaller than state (address, city, county, zip)
3. All elements of DATES (except year) including DOB, admission, discharge, death, ages over 89, dates indicative of age
4. Telephone, fax, SSN#s, VIN, license plate #s
5. Med record #, account #, health plan beneficiary #
6. Certificate/license #s
7. Email address, IP address, URLs
8. Biometric identifiers, including finger & voice prints
9. Device identifiers and serial numbers
10. Full face photographic and comparable images
11. *Any other unique identifying #, characteristic, or code*

The Privacy Rule:
Parents and Minors

HIPAA generally defers to state law concerning the relative rights of parents and minors. In this module, the terms "individual" or "patient" mean:

- Parents and legal guardians may generally exercise the HIPAA rights of their minor children;

- Patients 18 or older, or with emancipated or "mature minor" status, may exercise their own rights under HIPAA.

  If you are in doubt about a patient's status or have questions about the legal definition of emancipation or "maturity," check with the agency's legal counsel.

- A minor patient may exercise HIPAA rights regarding matters involving diagnosis or treatment relating to certain conditions (e.g., sexually transmitted diseases, drug or alcohol dependency, and pregnancy).

PHI and Research

Specific procedures may allow PHI to be used or disclosed for research purposes:

- Records can be de-identification.
- Written authorization may be obtained from the patient for research use or discloser.
- The Institutional Review Board (IRB) may grant a waiver of written authorization.
- Only data needed to prepare work for research purposes only may be disclosed.
- Special provisions may allow for research using a decedent's PHI.

General Data Disclosures

An agency may use or disclose demographic information and the dates of treatment for the purpose of raising funds for its own benefit, without an authorization.

- Example: "Between January and June we treated 47 patients under 18, 20% of whom had family incomes under $25,000 per year.

General Data Disclosures

- An agency must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of uses, disclosures, or requests.

05 Effect on Clinical Research

Clinical Research is Uniquely Affected by the Regulations

There are specific methods that allow PHI to be used or disclosed for research purposes:
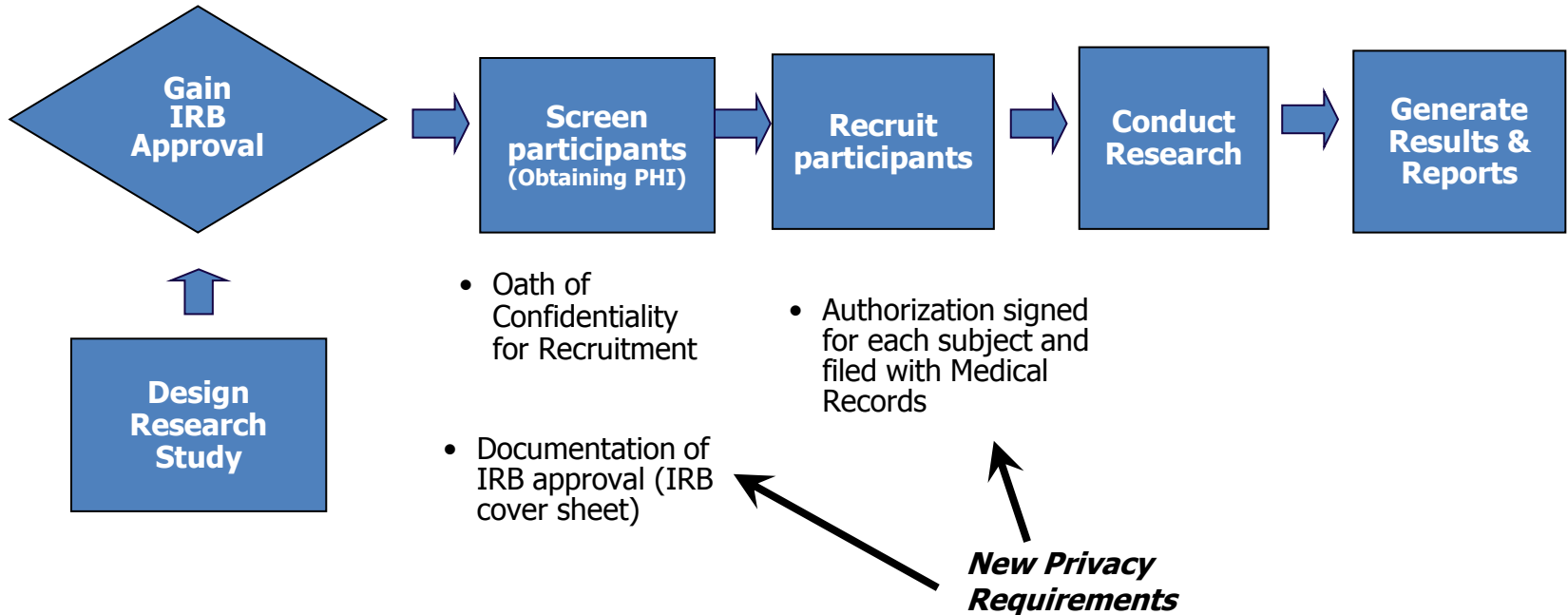
- All data are de-identified (according to the specific standards of the Privacy Rule).
- A limited data set is collected and released (according to the specific standards of the Privacy Rule).
- A patient gives a written authorization that his or her data may be used and/or disclosed.
- The Institutional Review Board (IRB) may grant a waiver of written authorization.
- Data are collected for preparatory work for research purposes only (according to the specific standards of the Privacy Rule).
- Special provisions are in place for research on a decedent's PHI.

Notice of a Person's Rights to Control His or Her PHI

An agency must distribute to each patient at the first treatment encounter, and obtain written acknowledgment of receipt of, a "Right to receive Notice of Privacy Practices":

- Describing how the agency may use and disclose PHI.
- Describing the rights the individual has to control his or her health information.

Impact on Clinical Research

Gain IRB Approval → Screen participants (Obtaining PHI) → Recruit participants → Conduct Research → Generate Results & Reports

Design Research Study → Gain IRB Approval

- Oath of Confidentiality for Recruitment

- Documentation of IRB approval (IRB cover sheet)

- Authorization signed for each subject and filed with Medical Records

New Privacy Requirements

06 Implementation at UMHS

Research
Implementation at UMHS

◆ HIPAA allows either an IRB or a "Privacy Board" to grant a "waiver of authorization" for use or disclosure of PHI for research purposes (including creation/maintenance of research databases)

◆ At UMHS, the Privacy Board also will assist in other ways, including:

❖ Certifications for reviews preparatory to research

❖ Certifications for research on decedents' information

❖ Approval of data use agreements

❖ Clearinghouse/expertise on privacy issues relevant to human subjects research projects

◆ A privacy board is not authorized to review and approve research under the Common Rule

Research
Implementation at UMHS

◆ HIPAA requires covered entities (e.g., UMHHC) to "account" for many research-related disclosures made without patient authorization

◆ Exceptions:

    ◆ internal <u>uses</u> do not need to be tracked

    ◆ disclosures made through a limited data set with a data use agreement do not need to be tracked

    ◆ disclosures of "deidentified data" do not need to be tracked (no information listed [HERE](#) included in the data set)

    ◆ disclosures made in studies involving more than 50 subjects do not need to be tracked *if* we keep a list available of all such studies, including title, PI, and contact information

◆ Policies/procedures for accounting are under development

Research
What Does HIPAA Mean for You?

- No PHI in Research
  - If you are conducting a project without use of PHI, HIPAA does not apply but IRBMED's informed consent template must be used for all new projects and scheduled continuation reviews beginning April 1
  - *Caution!*
  - If you do a blood test or radiological scan or other procedure only for research purposes, and not related to treatment, the information may not be PHI and your project is not regulated by HIPAA; *but*
  - If the test or results information passes through the subject's UM electronic medical record ("EMR") (because the medical record number is used and/or information is derived from and/orposted to the EMR or other clinical information systems), then HIPAA may apply

What Does HIPAA Mean for You?

- Some research-related disclosures are "grandfathered" under HIPAA
  - "Express *legal* permission" (usually written permission) from the individual to use or disclose their PHI for research
  - Written informed consent obtained before April 14, 2003
  - Waiver granted by IRB before April 14, 2003 (but if subject is later consented, consent must be HIPAA-compliant)

Research
Application: Multicenter Trials

Multicenter Trials

- Four ways to share PHI with other centers:
    - Written permission from the subject/patient (authorization)
    - Waiver from IRB or Privacy Board
    - Limited Data Set with Data Use Agreement
    - Deidentified data (nothing on "PHI" list)
- form in advance.

Research
Application: Multicenter Trials

- When we need information from other centers for our own research projects:
  - The updated IRBMED informed consent template is intended to comply with the privacy rule and to allow *any* health care provider or health plan to disclose PHI to us (or UMHHC to disclose PHI to our co-investigators) for research purposes.
  - However, every site may have its own rules and policies.
  - If another site or a sponsor requires an additional form to be signed by your subject, IRBMED must review and approve that

07 DICOM数据的传输

Digital Imaging and Communications in Medicine（DICOM）

- DICOM（Digital Imaging and Communications in Medicine）即医学数字成像和通信，是医学图像和相关信息的国际标准（ISO 12052）。它定义了质量能满足临床需要的可用于数据交换的医学图像格式。

- DICOM被广泛应用于放射医疗，心血管成像以及放射诊疗诊断设备（X射线，CT，核磁共振，超声等），并且在眼科和牙科等其它医学领域得到越来越深入广泛的应用。在数以万计的在用医学成像设备中，DICOM是部署最为广泛的医疗信息标准之一。当前大约有百亿级符合DICOM标准的医学图像用于临床使用。

关于PHI的传输

- 一些JI项目需要在PUHSC和UM之间以DICOM格式共享数十或数百个放射图像。由于DICOM格式将受保护的健康信息（PHI）嵌入图像文件的元数据中，因此必须具有能够确保正确管理和传输这些图像的解决方案。

- 我们开发了一种高度自动化的解决方案，用于去除大量DICOM图像的识别，加密和传输。除了将文件传输到JI服务器和从JI服务器传输文件以及生成PGP公钥之外，不需要用户干预。

关于PHI的传输

- 一旦发件人将这些图像移动到发件人端（PUHSC或UM）上的JI服务器上的预定义文件夹，我们的程序将找到所有DICOM或压缩的DICOM文件，然后通过删除包含的八个DICOM字段自动取消识别DICOM文件PHI。

- 取消标识的DICOM图像文件将被移动到暂存文件夹。然后，我们的程序将使用接收用户的PGP公钥以批处理模式加密暂存文件夹中的文件。加密的文件放入传输文件夹。

- 使用能够处理PUHSC和UM之间不稳定的互联网连接的现有JI数据共享解决方案，传输文件夹中的文件将每五分钟自动同步到JI服务器（UM或PUHSC）的另一端。传输的文件只能由具有相应PGP私钥的接收器使用。

- 我们期待与JI研究人员合作开发定制解决方案，以满足不同JI项目的独特数据管理和分析需求。

感谢您的聆听

临床研究注册

北医三院临床流行病学研究中心
曾 琳
zlwhy@163.com

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

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）

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.

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 ical Journal

Conflicts of Interest

ICMJE INTERNATIONAL COMMITTEE of MEIXCAL 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**

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

2004年9月，ICMJE

2004年11月WHO

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。

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。

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

免费向公众开放

向所有注册者开放

由非盈利性机构负责管理

可以实现电子检索

包含有效资料和最少资料等

- 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<u>具体标准</u>。WHO一级注册机构满足<u>ICMJE</u>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

International Clinical Registry Platform

About

Registry Network

Search portal

Unambiguous trial id

Reporting of findings

News and events

Publications

Clinical trials in chil

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

Topics
es
/Countries

ces
andards for Clinical Trial

material

中国临床试验注册中心

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

NIH U.S. National Library of Medicine

ClinicalTrials.gov

Find Studies ▼   About Studies ▼   Submit Studies ▼   Resources ▼   About Site ▼

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 275,028 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 ❶
- ○ Recruiting and not yet recruiting studies
- ● All studies

Condition or disease ❶ (For example: breast cancer)
[   ] X

Other terms ❶ (For example: NCT number, drug name, investigator name)
[   ] X

Country ❶

北医三院临床流行病学研究中心

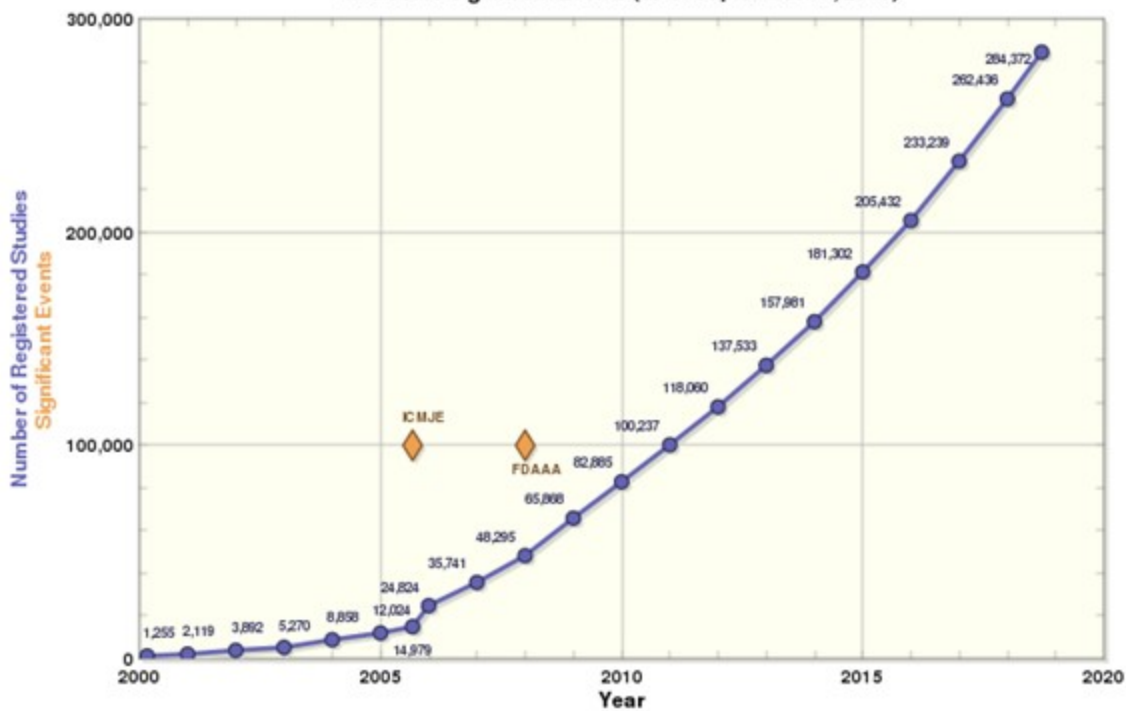| Study and Intervention Type (as of September 17, 2018)		Number of Registered Studies and Percentage of Total	Number of Studies With Posted Results and Percentage of Total***
Total		284,665	32,653
Interventional		225,986 (79%)	30,756 (94%)
Type of Intervention*	Drug or biologic	131,373	24,475
	Behavioral, other	70,323	5,470
	Surgical procedure	23,997	1,672
	Device**	28,072	3,865
Observational		57,376 (20%)	1,897 (6%)
Expanded Access		506	N/A

17

北医三院临床流行病学研究中心
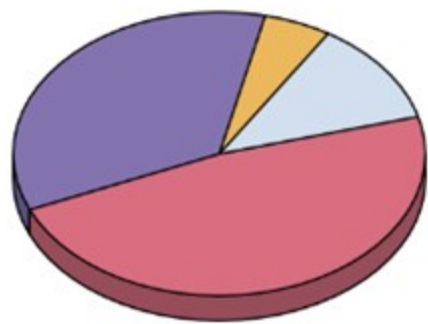
Non-U.S. only (48%)

U.S. only (35%)

Both U.S. and non-U.S. (5%)

Not provided (12%)
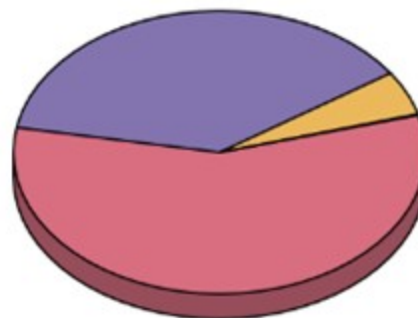
Non-U.S. only (57%)

U.S. only (38%)

Both U.S. and non-U.S. (5%)

**Number of Registered Studies Over Time
and Some Significant Events (as of September 17, 2018)**

Number of Registered Studies
Significant Events

- 1,255
- 2,119
- 3,892
- 5,270
- 8,858
- 12,024
- 14,979
- 24,824
- 35,741
- 48,295
- 65,868
- 82,885
- 100,237
- 118,060
- 137,533
- 157,981
- 181,302
- 205,432
- 233,239
- 262,436
- 284,372

ICMJE

FDAAA

Year

科i   Source: https://ClinicalTrials.gov

三院临床流行病学研究中心

Region Name	Number of Studies
World	284,665
East Asia	30,487
China	12,668
Hong Kong	1,711
Korea, Democratic People's Republic of	2
Korea, Republic of	9,407
Mongolia	22
Taiwan	5,617

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

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"

北医三院临床流行病学研究中心

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

Study and Intervention Type (as of September 17, 2018)		Number of Registered Studies and Percentage of Total	Number of Studies With Posted Results and Percentage of Total***
Total		284,665	32,653
Interventional		225,986 (79%)	
Type of Intervention*	Drug or biologic	131,373	
	Behavioral, other	70,323	
	Surgical procedure	23,997	
	Device**	28,072	
Observational		57,376 (20%)	
Expanded Access		506	

统计数据

已完成注册 17991

预注册 14036

补注册 3952

治疗性研究 10032

预防性研究 132

诊断试验 847

病因学研究 311

预后研究 194

流行病学研究 298

相关因素研究 1487

观察性研究 4280

● 华西中心，双语注册。在完成中、英文注册资料的上传后一周内获得注册号，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？

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

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15天内可获得注册号，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)

(1) 全球唯一试验注册号;

(2) 试验注册日期;

(3) 次级注册号;

(4) 资金来源;

(5) 主办者;

(6) 协办者;

(7) 责任联系人;

(8) 研究联系人;

临床试验
注册的内容

(9) 研究的题目;

(10) 正式的科学题目;

(11) 伦理许可;

(12) 条件;

(13) 干预措施;

(14) 纳入、排除标准;

(15) 研究类型;

(16) 试验启动日期;

(17) 目标样本量;

(18) 招募情况;

(19) 主要结局;

(20) 关键的次要结局。

临床试验注册基本流程

以
clinicaltrial.gov
为例

```
┌─────────────────────────┐
│ 在注册平台获取登录权限      │
│ (账户名、用户名和密码)      │
└─────────────────────────┘
            ↓
┌─────────────────────────┐
│ 登录注册系统，完整填写      │
│ 试验方案信息，提交试验      │
│ 方案注册系统(PRS)管理员    │
└─────────────────────────┘
            ↓
┌─────────────────────────┐
│ 注册平台检查试验方案的完    │
│ 整性，提供临床试验注册号    │
│ (NCT)数字，并发布注册方案   │
└─────────────────────────┘
            ↓
┌─────────────────────────┐
│ 完成试验方案注册           │
└─────────────────────────┘
            ↓
┌─────────────────────────┐
│ 同步临床试验的实施过       │
│ 程，更新注册信息           │
└─────────────────────────┘
            ↓
┌─────────────────────────┐
│ 临床试验完成数据分析       │
│ 后，同步在注册平台提交      │
│ 试验结果                  │
└─────────────────────────┘
            ↓
┌─────────────────────────┐
│ 试验结果发表后，添加发      │
│ 表引文的链接              │
└─────────────────────────┘
```

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。

注册信息的更新

- 开始纳入第一例受试者后更新研究实际开始时间。

- 纳入最后一例受试者后更新入组完成时间。

- 完成所有人随访后更新研究完成时间。

● 统计分析完成后更新主要的统计分析结果。

➢ 患者流程图

➢ 基线和人口学等特征描述

➢ 主要、次要结局指标
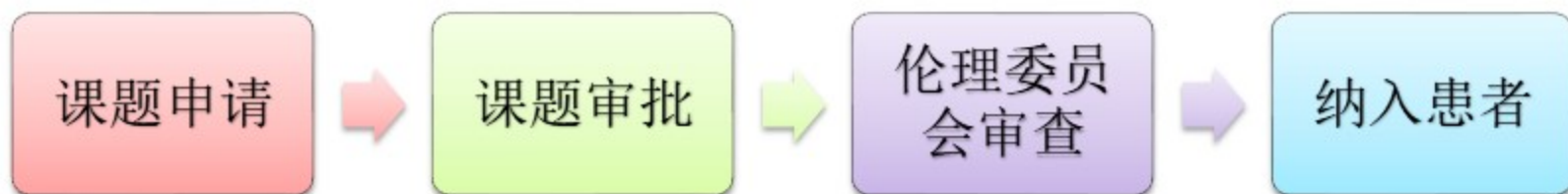
➢ 不良事件

- 《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。

| 完成试验注册 | ➡ | 纳入第一例受试者 | **预注册** |

| 纳入第一例受试者 | ➡ | 注册临床试验 | **补注册** |

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

课题申请 ➡ 课题审批 ➡ 伦理委员会审查 ➡ 纳入患者

临床研究流程的影响

```
课题申请  ➡  伦理
              预审查  ➡  课题审批
                                    ⬇
纳入第一例  ⬅  临床研究  ⬅  伦理委员会
患者          注册          审查
```
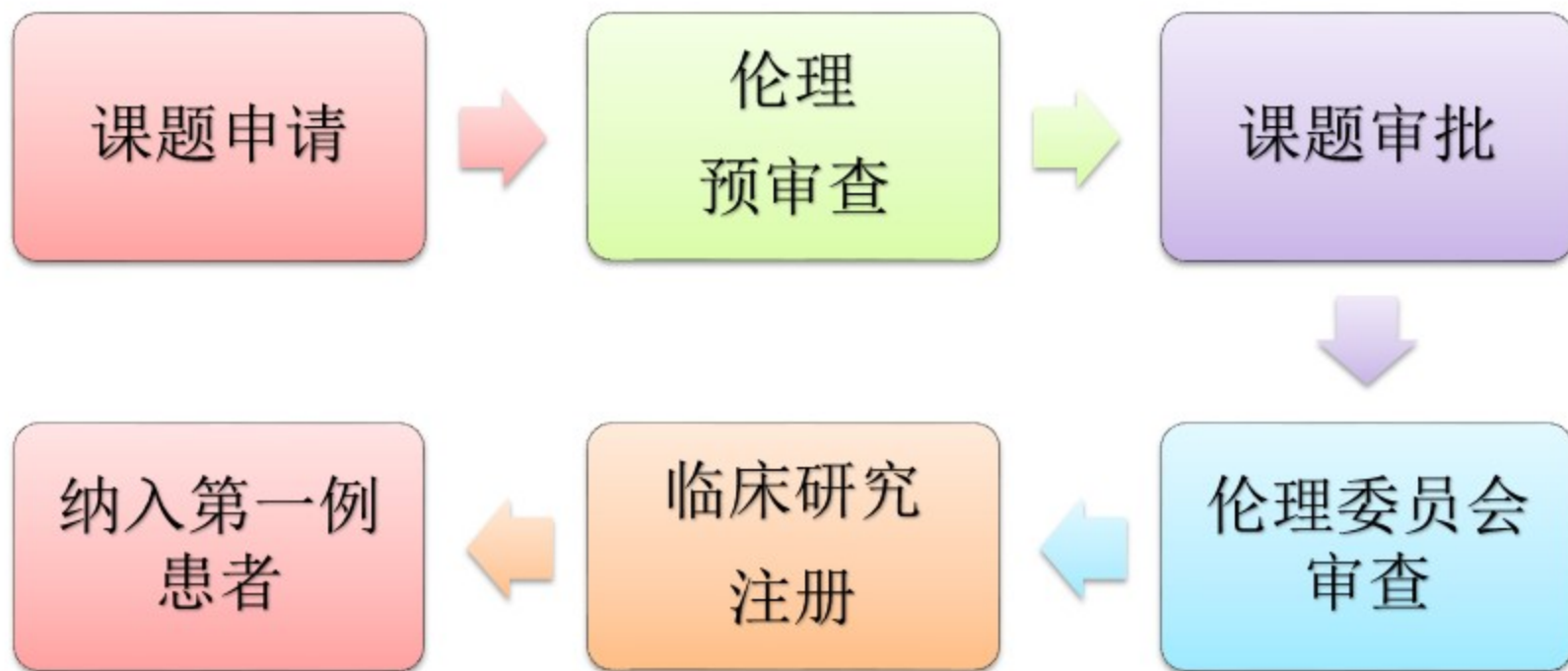
ChiCTR 中国临床试验注册中心
Chinese Clinical Trial Registry

世界卫生组织国际临床试验注册平台一级注册机构

今天是: 2018-09-19 星期三

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30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	ChiCTR1800017605	基因多态性对氯吡格雷和阿司匹林的影响--基于连续血小板计数检测的病例-对照研究 郑州大学人民医院（河南省人民医院）	相关因素研究	2018/08/06
历史版本	ChiCTR1800017603	基因多态性对阿司匹林的影响--基于连续血小板计数检测的病例-对照研究 郑州大学人民医院（河南省人民医院）	相关因素研究	2018/08/06

北医三院临床流行病学研究中心

ClinicalTrials.gov

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

Try our beta test site

Find Studies ▾   About Clinical Studies ▾   Submit Studies ▾   Resources ▾   About This Site ▾

Home > Find Studies > Search Results   Text Size ▾

1450 studies found for: aspirin

Modify this search | How to Use Search Results

| **List** | By Topic | On Map | Search Details |

+ Show Display Options   ⭳ Download   🔊 Subscribe to RSS

☐ Only show open studies

Rank	Status	Study
1	Unknown †	**Effect of Aspirin at the Acute Phase of Cerebral Ischemic Event.** **Condition:** Ischemic Stroke **Interventions:** Drug: Aspirin; Biological: blood sample
2	Active, not recruiting	**Therapeutic Control of Aspirin-Exacerbated Respiratory Disease (Aspirin)** **Conditions:** Asthma, Aspirin-Induced; Aspirin Exacerbated Asthma **Intervention:** Drug: Prasugrel
3	Recruiting	**Aspirin Supplementation for Pregnancy Indicated Risk Reduction In Nulliparas (ASPIRIN)** **Condition:** Premature Birth **Interventions:** Drug: Low dose aspirin; Drug: Placebo

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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/

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**

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?)
Display synonyms

Show 10 ˅ records per page

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 ... >>

北医三院临床流行病学研究中心

谢 谢！

曾 琳

北京大学第三医院

临床流行病学研究中心

更多临床流行病学相关问题敬请关注

微信公众号:**BYSYRCCE**