临床试验专用术语

实用小词典

中国临床研究专业网 组织翻译制作

www.ACRP.cn

翻　　译 Pipidan

校对排版 素人娱夫

责任编辑 harry97

ACRP(中国)给会员的信：求职中的盲点分析与对策

会员求职中的盲点：不知道如何撰写简历，第一关就被刷掉；不知道自己的优势劣势，病急瞎投医；不知道公司的薪资体系，乱报薪水要求；不了解公司内部结构，不知道如何在公司发展.....这些问题将在我们网站得到很好的解决。

网站创建 3 年多以来，与国内外知名的CRO公司、制药企业有很多学术合作和人才交流活动，比如昆泰，ICON，APEX,泰格，EXCEL和制药企业，诺华，罗氏，默克，礼来、赛诺菲、康弘、地奥、上海临床研究中心等公司，他们的医学部经理，人力资源部经理都是网站的高级顾问，随时在网站选拔人才，有的朋友还在网站担任版主职位。会员可以更直接得跟这些公司的高层对话，得到他们的指导和鼓励.

希望大家能把简历邮寄给ACRP人才库，我们将根据您的实际情况，请医药行业资深职业规划顾问针对你的个性特点，专业特长提出发展建议，同时也可以对你现在应该享受的薪资待遇进行评估，教授一些面试技巧，分析一下企业内部动态，帮助你了解你要去的企业的内部真实情况和薪资待遇。我们的服务会让你的职业生涯走得更顺、更辉煌！

如果你愿意加入我们人才库，请将简历请发送到harry97@acrp.cn 写上你的职业规划，求职意向，工作地点，目前薪水，期望薪水，目前拥有的人脉资源和技术特长(友情提醒：简历请用word文档作为附件，千万不要用pdf)。我们将尽快与您取得联系。

来吧！朋友们，我们一起来勇敢面对经济危机的寒冬吧！

记住 6 个写简历的要点：

1.扼要、精炼（Concise）

2.主次分明（Highlight）

3.实事求是（Factual）

4.动词说话（Action-oriented）

5.针对性强（Position-relevant）

6.精益求精（Critiqued）

站长 Harry97

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	北医肿瘤药理硕士，女，有经验，文字功底强，求SENIOR CRA北京7K New	Harry97 2009-3-30	4 / 60	2009-4-15 23:52 by silly198482
	预防医学，女，有罗氏、默沙东、AZ项目的数据管理经验，精通SAS.求上海、苏州工作6K New	Harry97 2009-3-27	6 / 134	2009-4-15 17:25 by xjwishing
	辩论：刚入行去CRO好还是药厂好？ 1 2	Harry97 2008-9-6	22 / 820	2009-4-15 09:25 by modification
	[【应界生求职】] 北京男硕士，MBA，有20个项目经验，熟练的应用SAS、SQL ，求统计师职位	Harry97 2009-4-15	1 / 12	2009-4-15 07:22 by Harry97
	北京某知名CRO实习经验，药学本科，女，求江浙江京沪CRA，待遇面议	Harry97 2009-3-30	7 / 84	2009-4-14 21:48 by xyypswr
	2军医大男硕士，外企CTA，参加过SOP、ICHGCP、Audit正规培训，求外企CRA，上海7K	Harry97 2009-3-29	7 / 126	2009-4-14 13:05 by kexiwang
	医学硕士、药学学士学位，女，求新药注册、报批专员、CRA工作（上海5k）	Harry97 2009-3-25	4 / 72	2009-4-14 12:05 by 何去何从
	中南大学临床药理研究所女硕士有工作经验求上海发展	Harry97 2009-3-13	13 / 163	2009-4-14 12:03 by 何去何从
	各地愿意兼职的CRA登记报名贴（重新开贴）	Harry97 2009-3-13	7 / 154	2009-4-14 11:20 by lyhlyhcra
	海龟，营养学硕士，英文流利，精通统计，求外企业医学部，统计部职位，北京8K	Harry97 2009-3-27	2 / 44	2009-4-14 10:03 by june.liu
	临床本科，男，有肿瘤药物（1.1类新药）II 期临床试验经验，求武汉CRA.5.5K/月	Harry97 2009-3-30	8 / 97	2009-4-14 09:54 by june.liu
	制药业外企CTA，熟悉ICH GCP，接受正规培训，求北京CRA工作，待遇面谈	Harry97 2009-3-30	4 / 109	2009-4-13 15:39 by 阿三
	[【应界生求职】] 上海交药学女硕士，能够用英语流利交流，应聘知名药企的医学部CRA	Harry97 2009-4-13	4 / 18	2009-4-13 12:34 by Heming0719
	[【有经验求职】] 女药剂师，求北京CRA工作	Harry97 2009-4-13	1 / 12	2009-4-13 10:24 by medkey-sh
	[【有经验求职】] 本科女，有20余项目经验，临床经理助理，曾是产科医生，英语6级	Harry97 2009-4-13	2 / 20	2009-4-13 10:06 by oooh
	[【应界生求职】] 应聘CRA ，临床药学 应届男硕士	Harry97 2009-4-13	0 / 7	2009-4-13 07:51 by Harry97
	[【应界生求职】] 生物化学与分子生物学硕士,求CRA职位，愿意从基础做起，	Harry97 2009-4-13	1 / 8	2009-4-13 07:37 by Harry97

	薪水不计			
	有经验华西医科大学理学男硕士求职上海CRA,期望4K/月 1 2	Harry97 2009-3-16	23 / 323	2009-4-11 23:20 by everyday
	北京CRO工作经验，本科，男，求北京CRA工作	Harry97 2009-3-24	6 / 98	2009-4-10 12:20 by buluodehuichen
	[全盟抄送]机会-凯维斯	cyclosporine 2009-3-23	7 / 165	2009-4-9 19:40 by modification
	流行病与卫生统计学女硕士求北京、上海发展	Harry97 2009-3-13	9 / 182	2009-4-8 19:51 by liaoqingping
	南中医女研究生，有CT经验，做过医学编辑，求北京CRA职位,4K,一周内到岗	Harry97 2009-4-1	4 / 60	2009-4-8 19:32 by angel3564
	[【有经验求职】] 药理女硕士，2年医生经历+1年肿瘤1类新药CRA，求北京CRA职位，待遇面谈	Harry97 2009-4-7	1 / 25	2009-4-7 20:47 by Harry97
	[【有经验求职】] 5年工作经验，有妇科、肿瘤、人体药代人脉资源，求北京项目经理职位	Harry97 2009-4-7	1 / 26	2009-4-7 20:22 by Harry97

临床试验专用术语实用小词典

ACRP.cn会员　　Pipidan 翻译　素人娱夫 校对排版

简化新药申请（ABBREVIATED NEW DRUG APPLICATION,ANDA）

参考其他新药申请数据的新药申请简略版。

Shortened version of a New Drug Application referencing data from other NDAs.

审查异议信件(ACTION LETTER)

美国食品药品管理局发给申请人的信函，表明对已提交申请的审查决定。*可批准函*表明待一些小问题解决后，申报的药品即可被批准；*未批准信函*表明申请中有重大缺陷需要更正。

A letter from the Food and Drug Administration to a sponsor indicating a decision on an application submittal. An upprovable letter indicates the product can be approved after minor issues are resolved. A approvable letter describes significant deficiencies in the application that require correction before the application can be considered.

积极治疗(ACTIVE TREATMENT)

临床试验中使用的一种治疗方法，通常是已知有效，并作为试验药物的阳性对照。

A treatment in a clinical trial where an active medication, known to be effective, is used, usually as a positive control compared to the investigational agent.

辅助治疗(ADJUVANT)

基本治疗方法以外的附加治疗方法。

Treatment used in addition to the primary therapy.

ADME

药物的吸收、分布、代谢和排泄。

Refers to the absorption, distribution, metabolism, and excretion of a drug compound.

行政视察(ADMINISTRATIVE LOOK)

a.检查正在进行的非验证性试验的数据或

b.检查正在进行的验证性试验的数据，用于后期试验设计、分配制造资源等但是均不会修改正在进行的试验。

a. Review of data from an ongoing nonconfirmatory study or

b. Review of data from an ongoing confirmatory trial that is used to make administrative decisions about the design of future trials, allocated manufacturing resources, and so on but NOT to modify the ongoing trial.

药物不良反应（ADVERSE DRUG REACTION ,ADR）

及不良反应（ADVERSE REACTION）
见不良经历（AE）。
See Adverse Experience (AE).

不良经历（ADVERSE EXPERIENCE，AE）

临床试验中受试者经历的任何不良症状或事件，不一定与研究药物有因果关系。也可称为不良反应、不良事件、药物不良反应（ADR）和副作用。
Any undesirable symptom or occurrence that a trial subject experiences during the clinical trial; it may or may not be considered related to the study agent. Also referred to us adverse reaction, adverse event, adverse drug reaction (ADR), and side effect.

咨询委员会（ADVISORY COMMITTEE）

委员会由美国食品药品管理局（FDA）委任的外部专家组成，主要审查递交至FDA的新药申请（NDA）数据。组成委员会的专家可根据需要来自各个领域。FDA的各个咨询委员会因治疗领域不同而异。委员会无权批准新药申请，只能向FDA建议申请的价值。
A committee of outside experts assembled by the Food and Drug Administration (FDA) to review data from a New Drug Application (NDA) submitted to the FDA. The committee consists of experts in the field and meets as needed. Many advisory committees to the FDA exist and differ for different therapeutic areas. The committee does not approve an NDA but only advises the FDA on the merit of the application.

修正案（AMENDMENT）

对于*新药研究（IND）申请*：指的是对提交给美国食品药品管理局的IND申请的更改或增加，通常包括新方案，现有方案的修改或新的研究者。
对于*新药申请(NDA)*：指对未批准的新药申请进行资料补充，如新的安全性信息或补充研究所得数据。
对于*方案*：指要求修订的试验方案的变更。
to an investigational New Drug (IND) Application: A change or addition to an IND filed with the Food and Drug Administration; generally, these include a new protocol, a change to an existing protocol, or a new investigator.
to a New Drug Application (NDA): A supplement to a pending NDA, such as a safety update or data obtained from a supplementary study.
to a protocol: A change in a study protocol requiring an amendment to the protocol.

递增剂量（ASCENDING DOSE）

逐渐增加用药剂量直至到达最大耐受剂量（MTD），通常在I期试验中研究。
Increasingly higher doses of a drug until a maximum tolerated dose (MTD) is reached.These studies are generally Phase I studies.

稽查（AUDIT）

对研究数据、方案程序、研究实施、阶段性研究报告和研究总结报告进行细致审查，以确定试验结论是否有效，试验实施是否合理。

A careful review of study data, protocol procedures, study conduct, and interim or final study reports to determine whether the conclusions are valid and whether the study has been carried out appropriately.

稽查跟踪（AUDIT TRAIL）

书面的文件、信函以及记录研究实施的报告如研究文档、病例报告表的更改和药物清点记录等。

Written record of documents, correspondences, and reports that documents study conduct, such as study files, changes to Case Report Forms, and drug accountability records.

基线（BASELINE）

研究开始前测定的标准，作为后续检测和观察的参考。

Measurements usually taken at the beginning of a study to serve as a reference for subsequent measurements or observations.

偏差（BIAS）

在研治疗方法以外的其它因素对研究结果造成的影响。

Influencing study results by factors other than the treatment being tested.

生物利用度（BIOAVAILABILITY）

给药后不同时间药物进入血循环（或机体其它组织）的量。

Determination of amount of drug detectable in blood (or other body tissues) at various times after administration.

生物等效性（BIOEQUIVALENCE）

用于描述一个药物与另一个类似药物的疗效比较（通常是一个非专利药品与一个已批准上市药品来对比）。如果能证明两者有等效性，那么试验药物就不再需要进行大量的临床试验来证明其安全性和有效性了。

Term used to describe comparable activity of one drug compound to another (usually a generic product to a product that has received approval). If bioequivalence can be demonstrated, the product does not have to undergo extensive clinical trials to demonstrate safety and efficacy.

生物制药学（BIOPHARMACEUTICAL）

指使用生物学技术研发的制剂。

Refers to pharmaceutical products developed using biotechnology.

BIRA

英国法规事务研究所。

British Institute of Regulatory Affairs.

设盲（BLINDING）

为防止研究结果出现偏差而设计的特异性对照试验。双盲试验中，患者和研

究者都不知道患者接受的是哪种治疗；单盲试验中，患者或受试者不知道接受的是哪种治疗；三盲试验中，研究者、患者和申办者都不知道治疗分配；开放性试验则是指所有当事人都知道接受的是哪种治疗。

Characteristic of a controlled study design to deter bias in interpretation of reported results. In a double-blind study, neither the patient nor the investigator knows which treatment the patient receives. In a single-blind study, the patient or observer does not know which treatment is being received. In a triple-blind study, the investigator, patient, and sponsor all are blinded to the study medication. The term open study refers to a trial where all parties may know the treatment the patient receives.

CANDA

电脑辅助的新药申请:通过电子方式向美国食品药品管理局（FDA）提交新药申请资料通。

Computed-Assisted New Drug Application; a method of filing a New Drug Application with the Food and Drug Administration where much of the information is transmitted electronically.

病历记录（CASE HISTORY RECORD）

包括受试者医学和人口统计学信息的医院图表、医疗档案或病人记录。“源文件”用来证明病例报告表中的信息的真实性。

The hospital chart, medical office file, or patient record containing medical and demographic information on the study subject. The ″source

document″ used to verify the authenticity of the information recorded in the Case Report Form.

病例报告表（CASE REPORT FORM，CRF）

临床试验中按照试验方案专门设计用来记录每一例受试者信息的表格，CRF 中需要收集的信息由方案来确定。

Form designed specifically for each protocol to collect data on each subject enrolled in a clinical trial. Information collected on the CRF is determined by the study protocol.

因果关系（CAUSALITY）

方案中定义不良事件与试验药物关系的术语（如：无关，可能有关，有关）。

Relationship between the adverse experience and the test agent in terms defined in the protocol (e.g., not reasonably attributable, possibly attributable, or reasonably attributable).

CBER

生物制品评价与研究中心，美国食品药品管理局的部门。

Center for Biologics Evaluation and Research, branch of the Food and Drug Administration.

CDER

药品评价与研究中心，美国食品药品监督局的部门。

Center for Drug Evaluation and Research, branch of the Food and Drug Administration.

CDRH

器械和辐射健康中心，美国食品药品监督局的部门。

Center for Devices and Radiological Health, branch of the Food and Drug Administration.

CFR

美国联邦法规。

Code of Federal Regulations.

临床研究（CLINICAL INVESTIGATION）

根据美国联邦法规（CFR 21 第 312.3 部分），临床研究是指一个或更多人类受试者分发或使用一种药物的实验。

According to Title 21, Part 3 12.3, of the U.S. Code of Federal Regulations, "means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects."

临床研究者（CLINICAL INVESTIGATOR）

*参见*研究者。

See Investigator.

临床研究助理（CLINICAL RESEARCH ASSOCIATE，CRA）

申办者任命的有资格对临床试验过程进行监督的个人，是申办者与研究者或研究基地间沟通的桥梁。也称为临床研究专家（CRS），医学研究助理（MRA）和监查员。

A qualified individual working with the sponsor to oversee the progress of a clinical trial; the liaison between the sponsor and the investigator/site. Also referred to as Clinical Research Scientist (CRS), Medical Research Associate (MRA), and Monitor.

临床研究协调员（CLINICAL RESEARCH COORDINATOR，CRC）

通常是护士或其他护理专业人员，在研究基地中管理日常的临床研究工作，包括填写病例报告表，保存研究文件，并协助研究者。

Usually a nurse or other health professional, this individual is the study site's organizer of day-to-day conduct of study activities, including completing Case Report Forms, maintaining study files, and assisting the investigator.

临床研究协议（CLINICAL STUDY AGREEMENT，CSA）

*参见*合同。

See Contract.

临床试验（CLINICAL TRIAL）

按照正式的研究计划（方案）对某种材料（如：试验药物，器械）的效果，或对某种疾病的处理方法（如：手术，放射）的系统性研究。临床试验一般是指治疗方法的评价（药物，手术等），但预防、检查或诊断的方法也可能是临床试验的目的。

在制药业中，临床试验一般是指医药产品或医疗器械在人体（病人或健康志愿者）中进行的系统性研究，以发现或证实试验产品的不良反应，明确药物的疗效和安全性。此外，临床试验可能研究试验药物的吸收、分布、代谢和排泄以及药物的相互作用。

The systematic investigation of the effects of materials (e.g., investigational drugs, devices) or methods (e.g., surgery, radiation) on a disease state conducted according to a formal study plan (protocol). Generally, a clinical trial refers to the evaluation of treatment methods (drugs, surgery, etc.), although methods of prevention, detection, or diagnosis may also be the objective of a clinical trial.

In the pharmaceutical industry, clinical trials are typically a systematic study of a medicinal product or device in human subjects (patients or nonpatient volunteers) in order to discover or verify the effects of and identify adverse reactions to investigational products in order to ascertain the efficacy and safety of the investigational agents. Also, clinical trials may study the absorption, distribution, metabolism, and excretion as well as the pharmacodynamic interaction of investigational agents.

减免临床试验[CLINICAL TRIAL EXEMPTION，CT(X)]

仅提交简要资料（化学、药学、毒理学和志愿者研究）即可快速批准临床试验的途径。

A means of obtaining rapid approval of clinical trials by submitting only summary data (chemistry, pharmacology, toxicology, and volunteer studies).

盲码破译信封（CODE BREAKER）

一个密封的信封或标签，包含有每个受试者所接受试验药物的身份，试验出现紧急或异常情况时按方案和/或申办者要求打开。

A sealed envelope or label that contains the identity of the test agent for each study subject; should be opened only under emergency or unusual circumstances, as specified by the protocol and/or the study sponsor.

合作研究者/次级研究者（COINVESTIGATOR/SUBINVESTIGATOR）

协助主要研究者开展临床试验的医生或有资质的个人。FDA 研究者明细第 6 项中列出（参见 FDA 1572 表格）。*次级研究者* 是第一类。

A physician or qualified individual who assists the Primary Investigator in the conduct of the clinical trial; listed under item 6 of the FDA Statement of Investigator (Form FDA 1572).

Subinvestigator- is the preferred term.

联合治疗（COMBINATION THERAPY）

联合使用两种或两种以上的方法治疗疾病，如手术、放疗、化疗的方法交替或一起使用。

The use of two or more modes of treatment-e.g., surgery, radiotherapy, drug therapy-in combination, alternately or together, to treat a disease.

慈善用药（COMPASSIONATE USE）

美国食品药品管理局法规中指出在某些情况下可对个别患者使用试验药物。

Circumstances under which certain Food and Drug Administration regulations may be exempt to allow the use of an investigational agent for a single patient.

依从性（COMPLIANCE）

患者：指患者按照方案要求服用试验药物的遵循程度。

方案：指按照研究方案实施试验情况。

Patient: A term referring to the degree to which the patient has followed the instructions and dosing requirements of the protocol.

Protocol: Refers to adherence to the procedures defined in the study protocol.

验证性研究（CONFIRMATORY STUDY）

为药品注册审批所需提供药物疗效重要评价依据而实施的临床研究。此类研

究多为双盲随机对照试验。

Any clinical study designed to provide the substantial evidence of efficacy required for regulatory approval. These studies are typically double blind with a randomized control group.

合同（CONTRACT）

即：临床研究协议[CSA],临床试验协议[CTA]）

Clinical Study Agreement [CSA], Clinical Trial Agreement [CTA]

研究者（或机构代表）和申办方代表签署的并注明日期的文件，阐述了试验资金问题和责任分配。

A document signed and dated by the investigator (or institution representative) and sponsor representative that delineates agreements on financial matters and delegation/distribution of responsibilities.

合同研究组织（CONTRACT RESEARCH ORGANIZATION,CRO）

与申办者签订合同并能承担临床试验实施过程中申办者部分责任的独立机构。21 CFR 312.3 指出，CRO 是能为一个申办者承担一项或多项试验任务（如：设计试验方案、选择或监查研究、评价报告、准备整理递交至 FDA 的申报资料）的个人或组织。

An independent organization that contracts with the sponsor to assume some of the sponsor's responsibilities for conducting clinical trials. According to Title 21, Part 312.3, of the U.S. Code of Federal Regulations, "means a person that assumes, as an independent contractor with the sponsor, one or more obligations of a sponsor, e.g., design

of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration."

禁忌症(CONTRAINDICATION)

不推荐使用某种药物的指征或状态。

An indication or condition in which it is recommended that a drug NOT be administered.

对照组(CONTROL GROUP)

指接受标准治疗或使用安慰剂的患者组，其结果与接受试验治疗的“试验组”相比较。

The group of patients receiving the standard treatment or placebo used for comparison to results obtained in the "treatment group," the group of patients undergoing the experimental treatment regimen.

对照临床试验(CONTROLLED CLINICAL TRIAL)

将试验药物与安慰剂或其他有效治疗方法相对比的研究设计，受试者随机分配至各个治疗组。

A study design that compares the investigational drug with either placebo or with another treatment known to be effective against the disease in which subjects are randomly allocated to treatment groups.

协调中心(COORDINATING CENTER)

在多中心试验中负责协调和数据管理的临床试验基地。
A clinical research site that will coordinate activities and data management in multicenter trials.

协调研究者(COORDINATING INVESTIGATOR)

多中心试验中负责协调不同研究基地的其他研究者的研究者。
Investigator assigned to coordinate other investigators at different study sites in a multicenter trial.

交叉设计(CROSSOVER DESIGN)

每位入组病人按照特定的顺序接受两种或两种以上治疗的研究设计。
A study design that has each patient participate in two or more treatments in a specified order.

简历（CURRICULUM VITAE,CV）

研究者自身的培训经历和专业技能的总结，类似于履历。
Prepared by an investigator to summarize hisher training and expertise; similar to a resume.

数据(DATA)

从临床试验中获得的信息，通常记录在病例报告表（CRF）或临床实验室电子文件中。

Information obtained from a clinical trial, usually recorded on a Case Report Form (CRF) or clinical lab electronic file.

资料安全监测委员会

（DATA AND SAFETY MONITORING BOARD,DSMB）

对盲法试验中获得的数据进行审查，评估过度风险或显著疗效的独立机构。如果临床试验出现过度毒性反应，即使有足够证据表明治疗有效，DSMB也可停止试验。DSMB也称IDMC，即独立资料安全监测委员会。
An independent group that will review data from ongoing blinded clinical trials to evaluate excessive risk or profound efficacy. The DSMB can stop the clinical trial for excessive toxicity or if evidence is adequate to show treatment is beneficial. *Also called* IDMC, Independent Data Monitoring Committee.

数据核查(DATA AUDIT)

核查比较源文档的原始数据与转抄至病例报告表中的数据是否有差异。
Comparison of source documentation of original data to the data transcribed on a Case Report Form as a check for discrepancies.

数据编辑(DATA EDIT)

人工或自动比较数据，检测错误信息，以控制数据库的质量。
Comparison of data, manually or automated, to detect incorrect information for the purpose of clarification and quality control of the database.

数据管理(DATA MANAGEMENT)

自动和人工处理所有数据，从收集数据到转换为表格和图表形式的全过程。
All data-processing activities, automated and manual, beginning with data collection and transcription through the generation of tables and charts.

赫尔辛基宣言(DECLARATION OF HELSINKI)

见 **赫尔辛基宣言。**

See Helsinki, Declaration of

DHHS

健康与社会服务部。
Department of Health and Human Services.

文件(DOCUMENTATION)

描述临床试验方法和实施过程的任何形式的所有记录（文件、电子文件和光学文件），包括影响试验的因素及采取的措施。
All records in any form (documents, electronic files, and optical records) describing methods and conduct of a clinical trial, as well as factors affecting the trial and action taken.

剂量限制性毒性(DOSE-LIMITING TOXICITY)

指某剂量水平出现的毒副作用是调整剂量的决定因素。

A dose at which the level of toxicity is a factor in determining dose modifications.

剂量范围研究(DOSE-RANGING STUDIES)

评价不同剂量的试验药物的疗效和/或安全性的研究设计。

A study design to evaluate the effect and/or safety of different doses of an investigational agent.

双盲(DOUBLE BLIND)

见 **设盲。**

See Blinding.

脱落病例(DROPOUT)

临床试验过程中未能完成全部方案要求的试验参数的受试者。

A subject who does not complete all of the protocol-required parameters for a clinical trial.

DSMB

资料安全监测委员会。

Data and Safety Monitoring Board.

EC

欧洲共同体。

European Community.

有效性(EFFICACY)

药物能够改善疾病症状的指标。

A measure of a drug's ability to ameliorate the signs and/or symptoms of a disease.

EFPIA

欧洲制药业联合会。

European Federation of Pharmaceutical Industries and Associations.

EMEA

欧洲药物评价署。

European Agency for the Evaluation of Medicinal Products.

终点(ENDPOINT)

表明患者完成试验的预定事件（每份方案），由疾病状态（治愈，进展）或完成所有试验随访来表示。

A predetermined event (per protocol) that indicates a patient's completion of the trial, either by disease state (cure, progression) or by completion of all study visits.

伦理委员会（EC）

由医学专业人员和非医学专业人员组成的独立机构，其宗旨是保证临床试验的安全性真实性及维护试验受试者的权益。多数国家的伦理委员会对涉及到人体的任何试验都需要提出自己的观点。欧盟的伦理委员会相当于美国机构审查委员会（IRB）。

An independent group of medical and nonmedical professionals whose purpose is to verify that the clinical trial is performed safely, with integrity, and with respect to the rights of the human subjects. Most countries require that an EC provide a statement of its opinion on any research involving human subjects. The Ethics Committee is the European Union equivalent of the U.S. Institutional Review Board.

EU

欧盟。

European Union.

可评价患者(EVALUABLE PATIENT)

完全符合临床试验方案的要求，可用于评价试验药物安全性和有效性的患者。

Patient in a clinical trial who has satisfied all protocol requirements and may be evaluated for safety and efficacy in the analysis.

总结报告（研究者提供）[FINAL REPORT (by Investigator)]

每位研究者需要对临床试验进行总结（根据机构审查委员会[IRB]的具体要求），并以总结报告提交给 IRB 和申办者。

Each investigator is required to summarize the clinical trial (per specifications of their Institutional Review Board [IRB]) and submit it to the IRB and sponsor in a final report.

研究总结报告（FINAL STUDY REPORT）

或 医学总结报告（Final Medical Report）

关于已完成临床试验的一份完整而全面的描述，包括试验材料和方法，试验结果的显示和评价，统计分析和结果的关键性讨论。

A complete and comprehensive description of the completed study, including descriptions of experimental materials and methods, presentation and evaluation of the results, statistical analyses, and a critical discussion of the results.

美国食品药品管理局（FOOD AND DRUG ADMINISTRATION,FDA）

美国联邦政府的职能部门，主要负责食品、药品和化妆品的监管。

The federal agency responsible for regulating the sale of food, drugs, and cosmetics in the United States.

药物临床试验质量管理规范（GOOD CLINICAL PRACTICE,GCP）

临床试验设计、实施和报告的标准，以确保试验数据的科学性，保障受试者的权益。参照美国联邦法规 21 第 50、56、312、314、600、601、812 及 813 款。

A standard by which clinical trials are designed, implemented, and reported to assure that the data are scientifically sound and that the rights of the subjects are protected. Refer to Title 21, Parts 50, 56, 312, 314, 600, 601, 812, and 813 of the U.S. Code of Federal Regulations.

实验室质量管理规范（GOOD LABORATORY PRACTICE,GLP）

实验室研究的管理规范。参照美国联邦法规 21 第 58 款。

Regulations pertaining to research laboratories. Refer to Title 21, Part 58, of the U.S. Code of Federal Regulations.

药品生产质量管理规范（GOOD MANUFACTURING PRACTICE,GMP）

确保药品的生产和质量控制严格遵照适合其预定用途和产品规格的质量标准的质量保证。参照美国联邦法规 21 第 211 款。

That part of pharmaceutical quality assurance that ensures that products are consistently produced and controlled in conformity with quality standards appropriate for their intended use and as required by the product specification. Refer to Title 21, Part 211, of the U.S. Code of Federal Regulations.

赫尔辛基宣言(HELSINKI, DECLARATION OF)

临床试验中实施伦理的国际性文件。

International document concerning the ethical conduct of clinical trials.

ICH

国际协调会议。

International Conference on Harmonisation.

IDE

器械临床试验豁免。

Investigational Device Exemption.

IDMC

见 **资料安全监测委员会。**

See Data and Safety Monitoring Board.

赔偿(INDEMNIFICATION)

一份免除赔偿责任或第三方损害的法律文件，临床试验中通常指受试者遭受损害时，该文件可以保护研究者和/或医院或研究机构避免受到受试者（或亲属）提出的索赔问题的困扰。

A legal document indicating protection or exemption from liability for compensation or damages from a third party; usually protects an investigator and/or hospital or institution from claims made by the study subject (or relatives) that harm was caused to the subject as a result of participation in the clinical trial.

适应症(INDICATION)

试验药物拟定能治疗的疾病或医学问题。

The disease state or medical problem being evaluated with the study agent.

信息修订(INFORMATION AMENDMENT)

指的是对新药研究申请的修订（并非仅仅针对一个具体方案），提供补充信息如增加新的研究者。

Refers to an amendment to the Investigational New Drug Application (not necessarily to a specific protocol) that provides additional information, such as the addition of a new investigator.

知情同意书(INFORMED CONSENT FORM)

用来证实受试者是自愿参加临床试验的表格。试验相关的所有信息如研究目的、潜在利益和风险、受试者的权利和义务已经解释清楚，受试者的所有问题都得到解答后，由受试者本人或法定代理人签名。知情同意书和信息必须经过机构审评委员会审查批准。

Form used to confirm a trial subject's willingness to participate

voluntarily in a study. The subject or legal representative signs the form after all appropriate information about the trial, including objectives, potential benefits and risks, and subject rights and responsibilities, has been explained and all subject questions have been answered. The Informed Consent Form and information must be reviewed and approved by the Institutional Review Board.

视察(INSPECTION)

美国食品药品管理局、申办者、研究基地和/或申办方的合作组织实施的官方审查，其目的在于核实研究是否按照法规和指导方针，包括 GCP 要求来实施的。

An official audit conducted by regulatory authorities of the Food and Drug Administration, sponsor, or cooperative group at the site of investigation and/or the sponsor. The purpose of the inspection is to verify adherence to applicable regulations and guidelines, including those of Good Clinical Practice.

机构审查委员会（INSTITUTIONAL REVIEW BOARD,IRB）

依据美国联邦法规 21 第 56 款的要求成立的，由医学专业人员和非医学专业人员组成的独立机构，其职责是保障任何参加人体试验的受试者的安全和权益。

An independent body of medical and nonmedical members established according to requirements outlined in Title 21, Part 56, of the U.S. Code of Federal Regulations. The IRB, usually institution specific, is responsible for the initial and continuing approval of research

involving human subjects, as well as for verifying the protection of safety and rights of those human subjects.

试验药物或产品(INVESTIGATIONAL AGENT OR PRODUCT)

临床试验研究的药物、安慰剂或器械。
A pharmaceutical product, placebo, or device being used in an investigational clinical trial.

研究性新药(INVESTIGATIONAL NEW DRUG)

按照美国联邦法规 21第312.2款的规定，研究性新药是指用于临床研究的新药、抗生素或生物制品，也包括用于体外诊断目的的生物制品。
According to Title 21, Part 312.2, of the U.S. Code of Federal Regulations, ″means a new drug, antibiotic drug, or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes.″

新药研究（IND）申请

INVESTIGATIONAL NEW DRUG (IND) APPLICATION

向美国食品药品管理局申请研究新药在人体进行临床试验的过程，包括药理学、化学、毒理学、临床前研究结果和后续的研究计划等信息。
In the United States, process by which investigational new drugs are registered with the Food and Drug Administration for administration to human subjects in clinical trials; includes information on pharmacology, chemistry, toxicology, previous clinical studies

results, and future study proposals.

研究者（主要研究者）INVESTIGATOR (Principal Investigator)

作为研究组的领导人物，主要研究者（通常是专业医生或牙科医生）要负责临床试验的实施并确保受试者的安全和福利。要在研究者声明上签字（FDA 1572表格）。根据美国联邦法规 21第312.2款的规定，主要研究者是指具体实施临床研究（也就是：在他的直接指示下将试验药物分发给受试者）的个人。如果临床试验由一组人员实施，研究者指这个组的负责人，这个组的其它人员称为*次级研究者* 。

As the leader of the investigational team, this individual (usually a physician or dentist) is responsible for conducting the clinical trial and ensuring the safety and welfare of the study subjects. The investigator signs the Statement of Investigator Form (Form FDA 1572). According to Title 21, Part 3 12.3, of the U.S. Code of Federal Regulations, "means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Subinvestigator" includes any other member of that team."

研究者手册(INVESTIGATOR'S BROCHURE)

有关试验药物在临床研究开始前已知信息的总结，包括临床前数据如化学、药理学、毒理学资料；动物及人体的药代动力学和药效学研究数据；既往临床研究结果。这些数据可为临床试验、安全性评价或预防措施提供合理依据。

手册应根据收集的新信息而不断更新。

Collection of all relevant information on the investigational product known prior to the start of a particular clinical trial, including preclinical data such as chemical, pharmaceutical, toxicological; pharmacokinetic and pharmacodymamic data in animals and in man; and the results of earlier clinical trials. The data should support the justification for the proposed trial and evaluate safety or precautions. The brochure should be updated on a continual basis as new information is gathered.

实验室证明(LABORATORY CERTIFICATION)

实验室的资格证书，证明该实验室能够熟练运用检测程序来开展所有实验，资格证书需要定期审核、测试后重新颁发，通常一年一次或一年两次。

A certificate given to a laboratory indicating that the laboratory is capable of performing all tests as required by use of a proficiency testing program. The certification is usually renewed on a biannual or annual basis after appropriate inspection and testing.

上市许可申请（MARKETING AUTHORIZATION APPLICATION,MAA）

在欧盟申请上市时需要向官方机构提交完整的信息档案，包括药物的化学、药剂学、生物学和临床研究数据。

A complete dossier of information, including chemical, pharmaceutical, biological, and clinical data, which is sent to a regulatory authority to support a request for marketing authorization in the European Union.

最大耐受剂量（MAXIMUM TOLERATED DOSE ,MTD）

受试者未出现不可耐受的副作用的最大给药剂量。

The dose determined to be the highest dose to give subjects without unacceptable side effects.

监查员(MONITOR)

参见 临床研究助理（CRA）。

See Clinical Research Associate (CRA).

监查(MONITORING)

申办方与研究者或研究组成员之间的联系人，以监督临床试验进展。

A contact by the sponsor with an investigator or member of the investigative staff that serves to further the progress of a clinical trial.

MOU

谅解备忘录。指美国食品药品管理局与其它管理机构之间允许相互视察的文件。

Memo of Understanding.A document between the Food and Drug Administration and other regulatory agencies that allows mutual inspection.

多中心试验(MULTICENTER TRIAL)

由多个研究基地的多个研究者按照同一个方案共同实施的临床试验。
A clinical trial conducted according to a single protocol at various investigational sites by various investigators.

新药申请（NEW DRUG APPLICATION,NDA）

向美国食品药品管理局申请将试验药物上市销售时应提交的完整信息档案，包括药物的化学、药剂学、生物学和临床研究数据。
The complete dossier of information submitted to the Food and Drug Administration to request marketing authorization for an investigational agent. The contents include chemical, pharmaceutical, biological, and clinical data.

新分子实体（NEW MOLECULAR ENTITY,NME）

(也称为新化学实体[NCE])
美国市场上从未有过的药物活性成分。
An active ingredient of a drug preparation that has not been previously marketed in the United States.

NIH

国立卫生研究院，是健康与社会服务部下属的一个联邦机构，由多个研究院和中心组成，致力于医学健康专业领域的研究。
National Institutes of Health. A federal agency under the Department of Health and Human Services that is composed of several institutes

and centers dedicated to specific areas of medical and health research.

非临床研究(NONCLINICAL STUDIES)

见 临床前实验。

See Preclinical Studies.

开放性研究(OPEN LABEL STUDY)

研究者和受试者均知道治疗方案、治疗药物和给药剂量的研究。

A study in which the treatment schedules, drug treatment, and doses are known to both the investigator and the subject.

OHRP

美国人类研究保护局。

Office of Human Research Protection.

结果(OUTCOME)

用于评价试验药物疗效的每位受试者的试验结果、状况或事件。

A result, condition, or event associated with individual study subjects used to assess efficacy.

药品说明书(PACKAGE INSERT)

提供已上市药品的处方信息和关于给药剂量、安全性和适应症等已知信息的

概述。

Refers to the prescribing information supplied with a marketed pharmaceutical product and summarizes known information about dosing, safety, and indications.

平行研究设计(PARALLEL STUDY DESIGN)

受试者在试验过程中随机入选一组治疗组的研究设计（与“交叉”设计相反）。

A study design where subjects are randomized to one treatment plan for the duration of the trial (as opposed to "crossover" design).

患者信息表(PATIENT INFORMATION SHEET)

在欧盟相当于知情同意书；也可指签署知情同意书前提供给受试者的信息。*可见* **知情同意书。** 也可指提供给受试者的试验药物服用指南。

European Community equivalent of Informed Consent Form; may also refer to the information provided to subjects prior to signing an Informed Consent Form. See also Informed Consent Form. May also refer to instructions to patients for administration of investigational agents.

药品(PHARMACEUTICAL PRODUCT)

指用于疾病的治疗、预防或诊断，旨在调节人体生理功能，并制备成合适的

给药形式的任何物质或化合物。

Any substance or combination of substances that has a therapeutic, prophylactic, or diagnostic purpose intended to modify physiological functions and presented in a dosage form suitable for administration to humans.

药效学（PHARMACODYNAMICS ,PD）

生理状态下药物相互作用的药理学研究的学科。

The science involving the pharmacology of the interaction of drugs in a physiological environment.

药代动力学（PHARMACOKINETICS,PK）

研究药物吸收、分布、代谢和排泄（ADME）的学科。

The science involving the absorption, distribution, metabolism, and elimination (ADME) of drugs.

药物经济学研究(PHARMACOECONOMIC STUDY)

研究治疗方法与经济利益相关性的学科。

The study of a specific treatment in relation to the economic benefits of the treatment.

药物流行病学(PHARMACOEPIDEMIOLOGY)

研究药物在人群和大量特殊人群中使用的学科。

The study of the use of drugs in the general population and large numbers of specific group types.

药理学(PHARMACOLOGY)

研究药物来源、性状、化学、活性和用途的学科。

The science involving drugs-their sources, appearance, chemistry, actions, and uses.

I 期临床(PHASE I)

新药研究申请完成后实施的第一期临床试验，目的是通过少量健康志愿者试验评价药物的安全性，药代动力学和剂量。

见 美国联邦法规 21 第 312.21 款。

The first clinical trials conducted after filing an Investigational New Drug Application. Generally aimed at establishing safety, pharrnacokinetics, and doses in a small number of normal volunteers.

See also Title 2 1, Part 3 12.21, of the U.S. Code of Federal Regulations.

II 期临床(PHASE I1)

在 I 期试验完成后实施，初步研究药物对目标适应症患者的疗效。一般是对经严格筛选后相对少量的患者进行随机对照研究。

见 美国联邦法规 21 第 312.21 款。

After Phase I studies, Phase I1 studies are the first look at efficacy in a given indication. They are usually randomized, tightly controlled studies using a relatively small number of carefully selected patients.

See also Title 2 1, Part 3 12.2 1, of the U.S. Code of Federal Regulations.

Ⅲ期临床(PHASE I11)

扩大试验范围，入选标准较宽松以观察研究药物在大量病人中使用的临床试验，也可在特殊人群中进行研究，如老年人科和小儿科。

见 美国联邦法规 21 第 312.21 款。

Clinical trials where the number of subjects is expanded and the inclusion criteria are less stringent to gain experience with the investigational agent in a large number of patients. Also, specific patient populations, such as geriatrics and pediatrics, may be investigated.

See also Title 2 1, Part 3 12.2 1, of the U.S. Code of Federal Regulations.

Ⅳ期临床(PHASE IV)

Ⅳ期临床试验通常指“上市后研究”，实施研究的原因很多，如：市场推广药品、市场销售反响或实施药物经济学研究和生活质量研究。申请药物新剂型或新适应症必须做 I/II 期临床试验。

Phase IV trials are often referred to as ″postmarketing studies″ and are done for a variety of reasons: to place the drug in the market,

to make marketing claims, or to conduct pharmacoeconomic studies and quality-of-life studies. New formulations of the drug or new indications must be investigated in Phase Ⅰ/Ⅱ clinical trials.

安慰剂(PLACEBO)

在临床研究中与试验药物的外形和味道相同,但无药理活性的物质，通常用于与试验药物对照。

An inactive substance made to appear identical to the test agent in appearance and taste used as a control in clinical studies.

PMA

上市前许可申请。指设备和市场应用。

Premarket Approval Application. Refers to devices and application for marketing.

上市后监测(POSTMARKETING SURVEILLANCE)

批准上市后，申办者监测药品在一般人群中的使用情况，以评价药品的不良事件。

Monitoring by the sponsor of the use of a drug in the general population after approved for marketing to evaluate adverse events.

临床前研究(PRECLINICAL STUDIES)

在人体临床试验前的研究，目地是获得新药信息，如吸收、分布、代谢、排

泄、毒性和致癌性。开展人体临床试验以后，临床前研究仍可继续进行。也称为非临床研究。

Studies done prior to human clinical trials and aimed at establishing information about a new drug, such as absorption, distribution, metabolism, elimination, toxicity, and carcinogenicity. Preclinical studies may continue after studies in humans are underway. Also referred to as Nonclinical Studies.

主要研究者(PRINCIPAL INVESTIGATOR)

见 研究者。

See Investigator.

方案(PROTOCOL)

试验药物、治疗方法或步骤的详细研究计划书。文件对研究背景、依据和目的进行说明，并具体概括了研究的设计、方法、组织和实施情况。

A detailed plan for the investigation of an experimental agent, treatment, or procedure. This document explains the background, rationale, and objectives of the trial and specifically outlines the design, methodology, organization, and condition of conducting the study.

方案-详细（计划）行政视察

(PROTOCOL-SPECIFIED (PLANNED) ADMINISTRATIVE LOOK)

数据行政视察，是方案计划的一部分。

An administrative look at the data that is planned as an integral part of the protocol.

随机化(RANDOMIZATION)

将受试者分配至平等的、类似的治疗组中的一种方法。
A method by which study subjects are assigned to a treatment group to obtain equal, comparable treatment groups.

随机码(RANDOMIZATION CODE)

依照受试者数目把试验用药物随机分配到一个治疗组中。药物会被事先分装好发给每一位受试者，受试者也会事先被随机分配到一个治疗组，随机分配的名单将会被密封到信封里或随机卡片中。
Investigational agent randomization to a treatment group by subject number. In addition to indicating the randomization on prepackaged drug for individual subjects, subjects may be randomized to a treatment arm by prerandomized numbers sealed in envelopes or randomization cards.

区域临床研究助理

（REGIONAL CLINICAL RESEARCH ASSOCIATER,CRA）

在某一区域进行监察。*也可见* 临床研究助理（CRA）。
Monitors located in geographic regions.
See also Clinical Research Associate (CRA).

风险-收益比(RISK-BENEFIT RATIO)

给予治疗或处理后风险与收益的关系。机构审查委员会（IRB）明确，研究具有潜在收益的前提下可适度存在风险。

The relationship between the risks and benefits of a given treatment or procedure. Institutional Review Boards determine that the risks in a study are reasonable with respect to the potential benefits.

安全性(SAFETY)

指药物在人体使用的安全性评价。也可指新药的安全性研究试验或已上市药物的安全性监察。

Refers to the evaluation of the safeness of a drug when used in humans. May refer to establishing safety of a new drug in an investigational trial or surveillance of the safety of a marketed drug.

严重不良事件（SERIOUS ADVERSE EXPERIENCE,SAE）

指任何重大损害、禁忌症、副作用或预防的事件，包括但不限于任何致命的、危及生命的、永久或显著致残的、需住院治疗或延长住院时间的事件。另外，先天性异常、恶性肿瘤和过量服药也是严重不良事件。

Any experience that suggests a significant hazard, contraindication, side effect, or precaution. This includes, but is not limited to, any experience that is fatal, life-threatening, or permanently or significantly disabling, or that requires inpatient hospitalization or prolongation of hospitalization. In addition, congenital anomaly, occurrence of malignancy, and overdose are always regarded as serious.

副作用(SIDE EFFECT)

见 不良事件（AE）。

See Adverse Experience (AE).

单盲(SINGLE BLIND)

见 设盲。

See Blinding.

原始数据(SOURCE DATA)

见 源文件。

See Source Document.

源文件(SOURCE DOCUMENT)

指受试者的病历、实验室检查报告、护理日志或任何正式文件中记录的原始观察或活动。源文件用于核实病例报告表中录入的数据。

Trial subject's medical chart, laboratory report, nurses' notes, or any official record documenting original observations or activities. Source documents are used for verification of the data entered on the Case Report Form.

源文件核查(SOURCE DOCUMENT VERIFICATION)

将病例报告表（CRF）中记录的数据与源文件的信息进行对比，以确保病例报告表中的数据真实完整的过程。

Process of assuring the validity and completeness of the data recorded in the Case Report Form (CRF) by comparing the information in the source document to that recorded on the CRF.

申办者(SPONSOR)

负责发起、组织和管理临床试验的个人或组织。根据美国联邦法规 21 第 312.3 款的规定，申办者指负责和发起临床研究的人。申办者可以是个人或制药公司、政府机构、学术机构、民间组织或其他团体。申办者不会亲自实施研究（申办者-研究者除外）。雇佣一个或多个人来实施研究的人是申办者，而不是申办者-研究者，那些雇员则是研究者。

Individual or organization that takes responsibility for initiation, organization, and management of a clinical trial. According to Title 21, Part 312.3, of the U.S. Code of Federal Regulations, "means a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, government agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators."

申办者-研究者(SPONSOR-INVESTIGATOR)

根据美国联邦法规 21 第 312.3 款，申办者-研究者是指发起并实施研究的人，并有权决定立即实施或取消研究。但不包括除此人以外的任何其他人。适用于研究者和申办者的相关要求，共同适用于申办者-研究者。

According to Title 21, Part 312.3, of the U.S. Code of Federal Regulations, "means an individual who both initiates and conducts an investigation and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor."

入组(STAGING)

根据疾病分类入选受试者进行临床试验的过程。

A process for categorizing the extent of disease for enrollment into a clinical trial.

标准操作规程(STANDARD OPERATING PROCEDURE)

实施临床试验的详细书面指南。

Detailed, written instructions for the management of clinical trials.

标准治疗(STANDARD TREATMENT)

目前正用于治疗某适应症且已被证明是有效的治疗方法。

The treatment currently being used for an indication and considered

to be of proven effectiveness.

研究者声明（SOI）表（即 FDA 1572 表格）

[STATEMENT OF INVESTIGATOR (SOI) FORM (also called Form FDA 1572)]
FDA 规定的实施所有临床试验都必须的文件，是美国新药研究（IND）申请注册的一部分。研究者签名表示认同临床试验中的应承担的主要责任；包括试验、研究者和主要责任的信息。
FDA-required document for all clinical trials conducted as part of a U.S. Investigational New Drug (IND) Application to register the investigator to do research for the IND; signed by investigator to indicate hisher acceptance of key responsibilities of the clinical trial; contains information about the trial, investigator(s), and key responsibilities.

分层(STRATA/STRATIFICATION)

基线时按某些特征选定的受试者亚组。
Subgroup of subjects selected by certain variables usually at baseline.

研究组(STUDY ARM)

研究的一个部分或具体治疗分组。
One part, segment, or specific treatment group of a study.

研究协调员(STUDY COORDINATOR)

见 临床研究协调员（CRC）。

See Clinical Research Coordinator (CRC).

研究药物(STUDY DRUG)

某个临床试验中研究的药物，可为固态、液态或气态（如：麻醉剂）的剂型。
The investigational agent(s) being studied in a particular clinical trial; may be in solid, liquid, or gas (such as anesthetic) form.

研究档案(STUDY FILES)

临床试验中存放在研究基地由研究者记录的文件。
The files located at the study site that pertain to an investigator's documentation of a clinical trial.

次级研究者/合作研究者(SUBINVESTIGATOR/COINVESTIGATOR)

具有协助主要研究实施临床试验资质的人，通常是医生或牙医。

可见 合作研究者/次级研究 和 *研究者（主要研究者）。*

A qualified individual (usually a physician or dentist) who assists the Principal Investigator in the conduct of a clinical trial.

See also Coinvestigator/Subinvestigator. and

Investigator (Principal Investigator).

受试者(SUBJECT)

参加临床试验的人（病人或健康志愿者）。受试者可以是：

a. 参加试验的健康志愿者；

b. 健康状况与试验药物用途无关的人；

c. 健康状况与试验药物用途有关的人；或

d. 试验中研究药物或对照药物的接受者。

根据美国联邦法规 21 第 312.3 款，受试者指参加研究的人，包括接受研究新药治疗的人和参加与研究药物对照组的人，受试者可为健康人也可是病人。

A human being (patient or nonpatient volunteer) participating in a clinical trial. The subject may be a a.healthy person volunteering in a trial, b.person with a condition unrelated to the use of the investigational product, c.person whose condition is related to the use of the investigational product, or d.recipient of the study drug being tested or a control. U.S. Code of Federal Regulations, ″means a According to Title 21, Part 312.3, of the human who participates in an investigation, either as a recipient of the investigational new drug or as a control. A subject may be a healthy human or a patient with a disease.″

替代指标(SURROGATE OUTCOME)

使用试验或测量，而不是一个临床事件来作为临床试验的结果。

The use of a test or measurement instead of a clinical event as an outcome of a clinical trial.

可揭标签(TEAR-OFF LABELS)

贴在试验药物上的一种特殊标签，其中一部分可撕下并可能含有研究药物的详细信息，如：随机编码。

Refers to a specific type of label for investigational agent where a portion of the package label can be torn off and may contain specific information about the investigational agent, e.g., the identity of the randomized code.

治疗方法(THERAPEUTIC)

即疗法。

Pertaining to treatment.

毒理学(TOXICOLOGY)

化合物的毒性药理学研究。

The study of the toxic pharmacology of a compound.

治疗组(TREATMENT GROUP)

接受试验药物治疗的病人组。

Group of patients receiving the experimental treatment regimen.

试验新药用于治疗(TREATMENT INVESTIGATIONAL NEW DRUG)

药物未被美国食品药品管理局批准上市前允许用来治疗病人的机制。

A mechanism by which a drug is approved for treatment use and made

available to patients before it has been approved by the Food and Drug Administration for sale.

三盲(TRIPLE BLIND)

见 **设盲。**

See Blinding.

非对照(UNCONTROLLED)

没有设置试验治疗方法与已有疗法（对照组）对比的研究。

A study where the investigational treatment is not being compared (by study design) to a concurrent treatment as a control.

非预期的不良事件(UNEXPECTED ADVERSE EXPERIENCE)

美国食品药品管理局规定：现有的研究者手册或研究计划风险信息或现行的新药研究申请中尚未提及性质、严重程度或发生频率的任何不良事件均为非预期的不良事件。

Defined by Food and Drug Administration regulations as any adverse experience that is not identified in nature, severity, or frequency in the current Investigator's Brochure or in the risk information described in the investigational plan or in the current Investigational New Drug Application.

非计划性行政视察(UNPLANNED ADMINISTRATIVE LOOK)

在方案中没有计划但试验开始后进行的官方数据核查。通常是试验药物看起来疗效太好或毒性太大时进行的数据分析。偶尔非计划性行政视察是必须的，但是必须保密进行，因为视察可导致试验结果无统计学意义。

An administrative look at data that were not anticipated in the protocol but arose after the trial was begun. Generally, this is done to analyze the data if the drug seems to be extremely effective or toxic. The need for unplanned administrative looks may arise occasionally, but these should be done sparingly since they can interfere with the statistical effectiveness of the results of the trial.

WHO

世界卫生组织。

World Health Organization.