ICH 三方协调指导原则　　E6 ICH GCP 指导原则

INTRODUCTION

前 言

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

临床试验管理规范（GCP）是设计、实施、记录和报告设计人类对象参加的试验国际性伦理和科学质量标准。遵循这一标准为保护对象的权利、安全性和健康，为与源于赫尔辛基宣言的原则保持一致以及临床试验数据的可信性提供了公众保证。

The objective of this ICH GCP Guideline is to provide a unified standard for the European Union (EU), Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

ICH-GCP 指导原则的目的是为欧盟、日本和美国提供统一的标准，以促进这些管理当局在其权限内相互接受临床数据。

The guideline was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organization (WHO).

本指导原则的发展考虑了欧盟、日本、美国，以及澳大利亚、加拿大、北欧国家和世界卫生组织（WHO）的现行 GCP。

This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.

在产生打算提交给管理当局的临床数据时应当遵循本指导原则。

The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.

本指导原则中确立的原则也可应用于可能影响人类对象安全和健康的其他临床研究。

1. GLOSSARY

1. 术语

1.1 Adverse Drug Reaction (ADR)　药品不良反应（ADR）

In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to a medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable

possibility, i.e. the relationship cannot be ruled out.

在一个新的药品或药品的新用途在批准之前的临床实践，尤其是治疗剂量尚未确定前，ADR 是指与药物任何剂量有关的所有有害的和非意求的反应都应被考虑为药物不良反应。该术语用于药品是指在药品与不良反应之间的因果关系至少有一个合理的可能性，即不能排除这种关系。

Regarding marketed medicinal products: a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

对已上市药品，ADR 指人对用于预防、诊断或治疗疾病或改善生理功能的药物在常用剂量出现的有害和非意求反应（参见 ICH 临床安全性数据管理指导原则：快速报告的定义和标准）。

1.2 Adverse Event (AE) 不良事件（AE）

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

在用药病人或临床研究对象中发生的任何不幸医疗事件，他不一定要与治疗有因果关系。因此，一个不良事件（AE）可以是与使用（研究）药物在时间上相关的任何不利的和非意求的征兆（包括异常的实验室发现）、症状或疾病，而不管其是否与药物有关（参见 ICH 临床安全性数据管理指导原则：快速报告的定义和标准）。

1.3 Amendment (to the protocol) 修改（试验方案）

See Protocol Amendment.

见试验方案修改

1.4 Applicable Regulatory Requirement(s) 适用的管理要求

Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products.

有关实施试验用药品临床试验的任何法律和法规。

1.5 Approval (in relation to Institutional Review Boards) 批准（机构审评委员会）

The affirmative decision of the IRB that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IRB, the institution, Good Clinical Practice (GCP), and the applicable regulatory requirements.

IRB 表示赞成的决定：指对一项临床试验已经进行审评，并可在 IRB、研究机构、GCP 和适用管理要

求的约束下由研究机构方实施。

1.6 Audit 稽查

A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

对试验相关活动和文件进行系统和独立的监察，以判定试验的实施和数据的记录、分析与报告是否符合试验方案、申办者的标准操作程序（SOP）、临床试验管理规范（GCP）以及适用的管理要求。

1.7 Audit Certificate 稽查证书

A declaration of confirmation by the auditor that an audit has taken place.

稽查员确认已进行稽查的声明。

1.8 Audit Report 稽查报告

A written evaluation by the sponsor's auditor of the results of the audit.

申办者方稽查关于稽查结果的书面评价

1.9 Audit Trail 稽查轨迹

Documentation that allows reconstruction of the course of events.

允许重复出现事件过程的文件。

1.10 Blinding/Masking 设盲

A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double-blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

一种使试验的一个或几个部分的人员不知道治疗分配的程序。单盲通常指对象不知道；双盲通常指对象、研究人员、监察员以及在某些情况下数据分析人员也不知道治疗分配。

1.11 Case Report Form (CRF) 病例报告表（CRF）

A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

设计用来记录试验方案要求向申办者报告的有关每一例对象的全部信息的印刷的、光学的或电子的文件。

1.12 Clinical Trial/Study 临床试验/研究

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

在人类对象进行的任何意在发现或证实一种试验用药品的临床、药理学和/或其他药效学作用；和/或确定一种试验用药品的任何不良反应；和/或研究一种试验用药品的吸收、分布、代谢和排泄，以确定药物的安全性和/或有效性的研究。术语临床试验和临床研究同义。

1.13 Clinical Trial/Study Report 临床试验/研究报告

A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report (see the ICH Guideline for Structure and Content of Clinical Study Reports).

在人类对象进行的任何治疗、预防或诊断剂的试验/研究的书面描述。临床和统计描述、陈述和分析全部列入该单份报告（见 ICH 临床研究报告的结构和内容指导原则）。

1.14 Comparator (Product) 对照（药物）

An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.

临床试验中用做对照的试验用药品或市售药物（即阳性对照）或安慰剂。

1.15 Compliance (in relation to trials) 依从性（关于试验的）

Adherence to all the trial-related requirements, Good Clinical Practice (GCP) requirements, and the applicable regulatory requirements.

遵循与试验有关的所有要求、临床试验管理规范（GCP）要求和适用的管理要求。

1.16 Confidentiality 保密性

Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

不得向未经授权的个人泄漏申办者所有的资料或对象的身份。

1.17 Contract 合同

A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

在两个或几个有关方之间的一份书面的、有日期和签字的协议，其中陈述了关于工作和责任和分派的安

排，以及关于财务问题的安排。试验方案可以作为合同的基础。

1.18 Coordinating Committee 协调委员会

A committee that a sponsor may organize to coordinate the conduct of a multicentre trial.
申办者组织的协调实施多中心试验的委员会。

1.19 Coordinating Investigator 协调研究者

An investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre trial.
被指定负责协调参加一项多中心试验的各中心研究者工作的一名研究者。

1.20 Contract Research Organization (CRO) 合同研究组织

A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.
与申办者订立契约完成一个或多个有关申办者方的试验任务和功能的个人或组织（商业性的，学术的或其他）。

1.21 Direct Access 直接访问

Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsor's monitors and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor’s proprietary information.
允许监察、分析、核对和复制任何对于评价临床试验有重要意义的记录和报告。直接访问的任何一方（如国内和国外的管理当局，申办者方的监察员和稽查员）应当受适用管理要求的缺书，采取一切合理的预防措施维护对象身份和申办者资料的保密性。

1.22 Documentation 文件

All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.
描述或记录试验的方法、实施和/或结果，影响试验的因素，以及采取的措施等的任何形式的记录（包括但不限于书面、电子、磁性和光学的记录，以及扫描、X 射线和心电图）。

1.23 Essential Documents 必需文件

Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced (see 8. Essential Documents for the Conduct of a Clinical Trial).
指各自和合在一起允许评价一个研究的执行情况和所得数据的质量文件（见 8.实施临床试验的必需文

件）。

1.24 Good Clinical Practice (GCP) 临床试验管理规范（GCP）

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

是临床试验设计、实施、执行、监察、稽查、记录、分析和报告的标准，它为数据和所报告结果的可信性和准确性提供了保证，并保护试验对象的权利、完整性和机密性。

1.25 Independent Data-Monitoring Committee (IDMC) (Data and Safety Monitoring Board, Monitoring Committee, Data Monitoring Committee)

独立的数据监察委员会（IDMC）（数据和安全监察委员会，监察委员会，数据监察委员会）

An independent data-monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial. 由申办者设立一个独立的数据监察委员会，它定期对研究进展、安全性数据和有效性终点进行评估，向申办者建议是否继续、调整或停止试验。

1.26 Impartial Witness 公平的见证人

A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

独立与临床试验、不受与试验有关人员的不公正影响的个人。如果对象或对象的合法接受代表人不能阅读，他/她将参与知情同意过程，并向对象阅读提供给她们的知情同意书和其他书面资料。

1.27 Independent Ethics Committee (IEC) 独立的伦理委员会（IEC）

An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving / providing favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

一个由医学专业人员和非医学专业人员组成的独立机构（研究机构的、地区的、国家的或超国家的审评机构或委员会），其职责是保证参加试验对象的权益、安全性和健康；并通过对试验方案、研究人员、设

施以及用于获得和记录试验对象知情同意的方法和材料的合理性进行审评和批准/提供起促进作用的意见以对这种保护提供公众保证

The legal status, composition, function, operations and regulatory requirements pertaining to Independent Ethics Committees may differ among countries, but should allow the Independent Ethics Committee to act in agreement with GCP as described in this guideline.

在不同的国家，独立的伦理委员会的法律地位、组成、职责、操作和适用的管理要求可能不用，但是应当如本指导原则所述，允许独立的伦理委员会按 GCP 进行工作。

1.28 Informed Consent 知情同意

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

一个对象在被告知与其作出决定有关的所有试验信息后，资源确认他或她参加一个特定试验的意愿过程。知情同意采用书面的、签字并注明日期的知情同意书。

1.29 Inspection 视察

The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority(ies).

管理当局在试验单位、申办者和/或合同研究组织或管理当局认为何时的其他机构对其认为与临床试验有关的文件、设备、记录和其他资源进行的官方审查的活动。

1.30 Institution (medical) （医学）研究机构

Any public or private entity or agency or medical or dental facility where clinical trials are conducted.

实施临床试验任何或私人的实体、代理机构、医学或齿科设施。

1.31 Institutional Review Board (IRB) 机构审评委员会（IRB）

An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

由医学、科学和非科学成员组成的一个独立机构，其职责是通过对试验方案及其修订本，获得受试对象

知情同意所用的方法和资料进行审评、批准和继续审评，确保一项试验的受试对象的权利、安全和健康得到保护。

1.32 Interim Clinical Trial/Study Report 临床试验/研究中期报告

A report of intermediate results and their evaluation based on analyses performed during the course of a trial.
根据试验进行过程中所做的分析写出的中期结果和评价的报告

1.33 Investigational Product 试验用药品

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
一种在临床试验中供试验的或作为对照的活性成分或安慰剂的药物制剂。包括一个已上市药品以不同于所批准的方式适用或组合（制剂或包装），或用于一个未经批准的适应证，或用于收集一个已批准用法的更多资料。

1.34 Investigator 研究者

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. See also Subinvestigator.
负责在一个试验单位实施临床试验的人。如果在一个试验单位是由一组人员实施试验，研究者指这个组的负责人，也称为主要研究者。见次级研究人员。

1.35 Investigator / Institution 研究者/研究机构

An expression meaning "the investigator and/or institution, where required by the applicable regulatory requirements".
表示“符合适用管理要求的研究者和/或研究机构”

1.36 Investigator's Brochure 研究者手册

A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects (see 7. Investigator’s Brochure).
与试验药品在人类对象中的研究有关的临床和非临床资料的汇编（见 7.研究者手册）

1.37 Legally Acceptable Representative　法律上可接受的代表

An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.

在适用法律下被授权代表一位未来的对象同意参加临床试验的个人，或司法人员或其他机关。

1.38 Monitoring 监察

The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

监督一个临床试验的进展，保证临床试验按照试验方案、标准操作程序（SOP）、临床试验管理规范（GCP）和适用的管理要求实施、记录和报告的活动。

1.39 Monitoring Report 监察报告

A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor's SOPs.

监察员在每一次现场访问和/或其他与试验有关的交流后，根据申办者的 SOP 写给申办者的书面报告。

1.40 Multicentre Trial 多中心试验

A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

按照一个试验方案，在一个以上试验单位实施，因此由一名以上研究者完成的临床试验。

1.41 Nonclinical Study 非临床试验

Biomedical studies not performed on human subjects.

不是在人类对象进行的生物医学研究。

1.42 Opinion (in relation to Independent Ethics Committee)

意见（与独立的伦理委员会相关）

The judgement and/or the advice provided by an Independent Ethics Committee (IEC).

由独立的伦理委员会（IEC）给出的评价和/或建议

1.43 Original Medical Record 原始医学记录

See Source Documents.

见源文件

1.44 Protocol 试验方案

A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments.

一个阐明试验的目的、设计、方法学、统计学考虑和组织的文件。试验方案通常也给出试验的背景和理论基础，但者这可以写在与方案有关的其他参考文件中。在 ICH 指导原则中，试验方案这一术语指试验方案和方案的修改。

1.45 Protocol Amendment 试验方案的修改

A written description of a change(s) to or formal clarification of a protocol.

对试验方案的改变或澄清的书面描述。

1.46 Quality Assurance (QA) 质量保证（QA）

All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

为保证试验的进行和数据产生、记录以及报告都符合临床试验管理规范（GCP）和适用管理要求所建立的有计划的系统活动。

1.47 Quality Control (QC) 质量控制（QC）

The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled.

在质量保证系统内所采取的操作技术和活动，以查证与试验相关的活动都符合质量要求。

1.48 Randomization 随机化

The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

为了减少偏倚，采用机遇决定分配的原理将试验对象分配倒治疗组或对照组的过程。

1.49 Regulatory Authorities 管理当局

Bodies having the power to regulate. In the ICH GCP guideline the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections (see 1.29). These bodies are sometimes referred to as competent authorities.

有权进行管理的基构。在 ICH GCP 指导原则中，管理当局一词包括审评所提交的临床数据和实施视察的机构（见 1.29）。这些机构有时指主管当局。

1.50 Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR) 严重不良事件（SAE）或严重药品不良反应

Any untoward medical occurrence that at any dose:

发生在任何剂量的任何不幸医学事件：

- results in death,
- 一 导致死亡
- is life-threatening,
- 一 危及生命
- requires inpatient hospitalization or prolongation of existing hospitalization,
- 一 需要住院治疗或延长住院时间

results in persistent or significant disability/incapacity, or

- 一 导致永久或严重的残疾/能力丧失，或
- is a congenital anomaly/birth defect
- 一 先天性异常/出生缺陷

(see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

（见 ICH 临床安全性数据管理指导原则，快速报告的定义和标准）

1.51 Source Data 源数据

All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are

contained in source documents (original records or certified copies).
临床试验中的临床发现、观察或其他活动的原始记录及其可靠副本中的全部资料，他们对于重建和评价试验是必要的。源数据包含在源文件中（原始记录或可靠副本）。

1.52 Source Documents 源文件

Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).
原始文件、数据和记录（如医院记录，临床和办公室图标，实验室笔记，备忘录，对象日记卡或评价表，药房发药记录，自动仪器的记录数据，在核对后做为准确副本的可靠复印件或抄件，显微胶片，摄影负片，缩微胶卷或磁介质，X 线，对象文件，以及保存在药房、实验室和与参与临床试验的医学技术部门中的记录。

1.53 Sponsor 申办者

An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.
对一个临床试验的发起、管理和/或财务负责的个人、公用、机构或组织。

1.54 Sponsor-Investigator 申办者－研究者

An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.
单独与其他人一起，发起并实施一个临床试验的个人。在他（们）的直接指示下，给对象服用、发给对象或由对象使用试验药品。该术语并不包括除了个人以外的任何人（如不包括一个公司或一个机构）。一个申办者－研究者的义务包括一个申办者和一个研究者两者的义务。

1.55 Standard Operating Procedures (SOPs) 标准操作程序（SOP）

Detailed, written instructions to achieve uniformity of the performance of a specific function.
为达到均一性完成一个特定职责指定的详细书面说明。

1.56 Subinvestigator 次级研究人员

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). See also Investigator.

在一个试验单位，在主要研究者指定和监督下的临床试验组中完成与试验有关的重要程序和/或作出与有关试验的重大决定的成员（如同事，住院医生，特别是研究生）。见研究者。

1.57 Subject/Trial Subject 对象/试验对象

An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

参加一个临床试验作为试验药品的接受者或作为对照的个人。

1.58 Subject Identification Code 对象识别编码

A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial related data.

研究者为每一名受试对象指定的独特识别号码，以保护对象的身份并在研究者报告不良事件和/或其他与试验有关数据时代替对象姓名。

1.59 Trial Site 试验单位

The location(s) where trial-related activities are actually conducted.

真正开展与临床试验有关活动的地方。

1.60 Unexpected Adverse Drug Reaction 非预期的药品不良反应

An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product) (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

一种不良反应，其性质或严重程度与现有的产品资料（如一种未批准试验用药品的研究者手册，或包装插入页/一个已经批准药物的产品性能摘要）不符的不良反应（见 ICH 临床安全性数据管理指导原则：快速报告的定义和标准）。

1.61 Vulnerable Subjects 弱势对象

Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

指受到不正当的影响而称为一个临床志愿者的人，他们可能由于期望（无论正当与否）参加试验而伴随的利益，或者拒绝参加会受到等级中资深成员的报复。有等级结构的团体的成员，如医学、药学、齿科或护理专业的学生，附属医院和实验室人员，制药公司的雇员，军人，以及被监禁的人。其他弱势对象包括无可救药的患者，住在福利院利的人，失业者或穷人，处于危急状况的病人，少数民族，无家可归者，流浪者，未成年者，和那些无能力给出知情同意的人

1.62 Well-being (of the trial subjects) 健康（试验对象的）

The physical and mental integrity of the subjects participating in a clinical trial.

参加临床试验对象的体格和精神的完整性。

2. THE PRINCIPLES OF ICH GCP　ICH-GCP 的原则

2.1 Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).

2.1 临床试验的实施应符合源自赫尔辛基宣言的伦理原则，与ＧＣＰ和适用管理要求一致。

2.2 Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

2.2 在开始一个试验之前，应当权衡个体试验对象和社会的可预见风险、不方便和预期的受益。只有当预期的受益大于风险时，才开始和继续一个临床试验。

2.3 The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.

2.3 试验对象的权利、安全和健康是最重要的考虑，应当胜过科学和社会的利益。

2.4 The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.

2.4 关于试验用药品可得到的非临床和临床资料应足以支持所提议的临床试验。

2.5 Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
2.5 临床试验应当有坚实的科学基础，有明确、详细描述的试验方案。

2.6 A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.
2.6 临床试验的实施应当遵循事先已经得到研究机构审查委员会（ＩＲＢ）/独立的伦理委员会（ＩＥＣ）批准/赞成的试验方案。

2.7 The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
2.7 一名合格医生或合格牙医的职责永远是给予对象医疗保健，代表对象作出医学决定。

2.8 Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
2.8 参与实施临床试验个每一个人应当在受教育、培训和经验方面都有资格完成他或她的预期任务。

2.9 Freely given informed consent should be obtained from every subject prior to clinical trial participation.
2.9 应当在参加临床试验前每一个对象获得自由给出的知情同意书。

2.10 All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
2.10 所有临床试验资料被记录、处理和储存的方式应当允许资料的准确报告、解释和核对。

2.11 The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
2.11 可能鉴别对象身份的记录的保密性应当得到保护，依照适用的管理要求尊重隐私和保密规定。

2.12 Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.
2.12 试验用药品应当按照适用的药品生产质量管理规范（ＧＭＰ）生产、处理和储存。试验用药品应按照已批准的方案使用。

2.13 Systems with procedures that assure the quality of every aspect of the trial should be implemented.

2.13 应当建立保证试验各方面质量的程序系统。

3. INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE (IRB/IEC)

机构审查委员会/独立的伦理委员会

3.1 Responsibilities 职责

3.1.1 An IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid to trials that may include vulnerable subjects.

3.1.1 IRB/IEC 应当保护所有试验对象的权利、安全和健康。应当特别注意那些可能包括有弱势对象的试验。

3.1.2 The IRB/IEC should obtain the following documents: 3.1.2 IRB/IEC 应当得到以下文件：
trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g. advertisements), written information to be provided to subjects, Investigator's Brochure (IB), available safety information, information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications, and any other documents that the IRB/IEC may need to fulfil its responsibilities.

试验方案/修改，研究人员申请用于试验的书面知情同意书及其更新件，对象招募程序（如广告），提供给对象的书面材料，研究者手册（ＩＢ），可得到的安全性材料，对象可获得的付款和补偿，研究人员的最新简历/或其他证明其资格的文件，以及 IRB/IEC 履行其职责所需要的任何其他文件。

The IRB/IEC should review a proposed clinical trial within a reasonable time and document its views in writing, clearly identifying the trial, the documents reviewed and the dates for the following:
IRB/IEC 应当在合理的时限内审查所提议的临床研究，提供书面审评意见，明确的确认试验、所审评的文件和日期如下：

- approval/ favourable opinion;
- 批准/赞成意见
- modifications required prior to its approval/favourable opinion;
- 在批准/赞成之前所需要的修改
- disapproval / negative opinion; and
- 不批准/负面的意见；和
- termination/suspension of any prior approval/favourable opinion.
- 中止/暂停先前的批准/赞成意见

3.1.3 The IRB/IEC should consider the qualifications of the investigator for the proposed trial, as documented by a current curriculum vitae and/or by any other relevant documentation the IRB/IEC requests.
IRB/IEC 应当参照现行简历和/或 IRB/IEC 要求的其他相关文件考虑所提议试验的研究人员的资格。

3.1.4 The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year.

IRB/IEC 应当根据人类对象的危险度，间隔一定事件对正在进项的试验继续审评，但至少每年一次。

3.1.5 The IRB/IEC may request more information than is outlined in paragraph 4.8.10 be given to subjects when, in the judgement of the IRB/IEC, the additional information would add meaningfully to the protection of the rights, safety and/or well-being of the subjects.

在 IRB/IEC 评价中，当补充资料对于保护对象的权利、安全和/或健康有意义时，IRB/IEC 可能需要比 4.8.10 段概述的给予对象的更多资料。

3.1.6 When a non-therapeutic trial is to be carried out with the consent of the subject's legally acceptable representative (see 4.8.12, 4.8.14), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials.

当一个将进行的非治疗试验是由对象的可接受的合法代表给出知情同意时（见 4.8.12.4.8.14），IRB/IEC 应当确定，所建议的方案和/或其他文件已经充分说明了相关的伦理学考虑，并符合这一类试验的适用管理要求。

3.1.7 Where the protocol indicates that prior consent of the trial subject or the subject's legally acceptable representative is not possible (see 4.8.15), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials (i.e. in emergency situations).

试验方案指出试验对象或其合法的可接受的代表的不可能先给出知情同意时（见 4.8.15），IRB/IEC 应当确定所提议的方案和/或其他文件充分说明了相关的伦理学考虑，并符合这一类试验的适用管理要求。

3.1.8 The IRB/IEC should review both the amount and method of payment to subjects to assure that neither presents problems of coercion or undue influence on the trial subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject.

IRB/IEC 应当审评支付给对象款项的数量和方式，以确认没有对试验对象的胁迫问题或不正当影响。给对象的支付应当按比例分配，而不是完全以对象完成试验而定。

3.1.9 The IRB/IEC should ensure that information regarding payment to subjects, including the methods, amounts, and schedule of payment to trial subjects, is set forth in the written informed consent form and any other written information to be provided to subjects. The way payment will be prorated should be specified.

IRB/IEC 应当保证，关于支付给对象的资料，包括支付方式、数量和支付给试验对象的时间表已列于知情同意书和将提供给对象任何其他书面资料上，应注明按比例支付的方式。

3.2 Composition, Functions and Operations 组成 、职能和操作

3.2.1 The IRB/IEC should consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial. It is recommended that the IRB/IEC should include:

IRB/IEC 应由合理数目的成员组成，他们全体都有审评和评价科学、医学和和所提议试验的伦理学方面的资料和经验。建议 IRB/IEC 应包括：

a) At least five members.

至少 5 名成员

b) At least one member whose primary area of interest is in a nonscientific area.

至少一名成员关心的重要领域时非科学领域；

c) At least one member who is independent of the institution/trial site.

至少一名成员独立于研究机构/试验单位。

Only those IRB/IEC members who are independent of the investigator and the sponsor of the trial should vote/provide opinion on a trial-related matter.

只有那些独立于试验研究者和申办者的 IRB/IEC 成员才能对一个试验的相关事项投票/提出建议。

A list of IRB/IEC members and their qualifications should be maintained.

应当提供一份 IRB/IEC 成员的名单和他们的资格表。

3.2.2 The IRB/IEC should perform its functions according to written operating procedures, should maintain written records of its activities and minutes of its meetings, and should comply with GCP and with the applicable regulatory requirement(s).

IRB/IEC 应但按照书面的操作程序完成其职责，应当保存其活动的书面记录和会议记录，并应当遵守ＧＣＰ和适用的管理要求。

3.2.3 An IRB/IEC should make its decisions at announced meetings at which at least a quorum, as stipulated in its written operating procedures, is present.

IRB/IEC 应当在达到其书面操作程序中规定的法定人数的正式会议上作出决定。

3.2.4 Only members who participate in the IRB/IEC review and discussion should vote/provide their opinion and/or advise.

只有参加 IRB/IEC 评审和讨论的成员才可投票/提出他们的评价和/或意见。

3.2.5 The investigator may provide information on any aspect of the trial, but should not participate in the deliberations of the IRB/IEC or in the vote/opinion of the IRB/IEC.

研究者应当提供试验各方面的资料，但不应当参加 IRB/IEC 的审议或 IRB/IEC 的投票/意见。

3.2.6 An IRB/IEC may invite nonmembers with expertise in special areas for assistance.

IRB/IEC 可邀请在特别领域有专门知识的非成员来帮助。

3.3 Procedures 程序

The IRB/IEC should establish, document in writing, and follow its procedures, which should include:

IRB/IEC 应当建立书面文件和遵循其程序，程序应包括：

3.3.1 Determining its composition (names and qualifications of the members) and the authority under which it is established.

确定其组成（成员单娥姓名和资格）和授权。

3.3.2 Scheduling, notifying its members of, and conducting its meetings.

安排时间，通知其成员，举行会议

3.3.3 Conducting initial and continuing review of trials.

对试验进行初始审评和继续审评

3.3.4 Determining the frequency of continuing review, as appropriate.

酌情确定继续审评的频度

3.3.5 Providing, according to the applicable regulatory requirements, expedited review and approval/favourable opinion of minor change(s) in ongoing trials that have the approval/favourable opinion of the IRB/IEC.

依照适用的管理要求，为已经获得 IRB/IEC 批准/赞成的正在进行的试验的较小修改提供快速审评和批准/赞成意见。

3.3.6 Specifying that no subject should be admitted to a trial before the IRB/IEC issues its written approval/favourable opinion of the trial.

说明在 IRB/IEC 书面签署对试验的批准/赞成意见之前不得接纳对象进入试验

3.3.7 Specifying that no deviations from, or changes of, the protocol should be initiated without prior written IRB/IEC approval/favourable opinion of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change of monitor(s), telephone number(s)) (see 4.5.2).

说明在方案的适当修改预先得到 IRB/IEC 的书面批准/赞成之前，不能偏离或改变试验方案，除非有必要排除对于对象的直接危害，或方案的改变只涉及试验的后勤或管理方面（如更换监察员，改变电话号码）（见 4.5.2）。

3.3.8 Specifying that the investigator should promptly report to the IRB/IEC:

说明研究人员应当立即报告 IRB/IEC 的事项：

a) Deviations from, or changes of, the protocol to eliminate immediate hazards to the trial subjects (see 3.3.7, 4.5.2, 4.5.4).

   偏离或改变方案以消除试验对象的直接危害（见 3.3.7，4.5.2，4.5.4）；

b) Changes increasing the risk to subjects and/or affecting significantly the conduct of the trial (see 4.10.2).

   增加对象风险的改变和/或明显影响试验实施的改变（见 4.10.2）

c) All adverse drug reactions (ADRs) that are both serious and unexpected.

   所有严重的和非预期的药品不良反应（ＡＤＲ）

d) New information that may affect adversely the safety of the subjects or the conduct of the trial.

对试验的进行或对象的完全可能不利影响的新资料。

3.3.9 Ensuring that the IRB/IEC promptly notify in writing the investigator/institution concerning:

确保 IRB/IEC 迅速通知研究者/研究机构的事项：

a) Its trial-related decisions/opinions.
与试验有关的决定/建议
b) The reasons for its decisions/opinions.
IRB/IEC 决定/意见的理由
c) Procedures for appeal of its decisions/opinions.
请求 IRB/IEC 决定/意见的程序

3.4 Records 记录

The IRB/IEC should retain all relevant records (e.g., written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) for a period of at least 3 years after completion of the trial and make them available upon request from the regulatory authority(ies).

IRB/IEC 应当保留全部有关记录（如书面的程序，成员名单，成员的职业/联系表，提交的文件，会议记录，以及往来信件）至完成试验后至少 3 年，并在管理当局需要时可以提供其书面程序和成员名单。

The IRB/IEC may be asked by investigators, sponsors or regulatory authorities to provide its written procedures and membership lists.

研究者、申办者和管理当局可向机构审查委员会/伦理委员会要求其提供书面运作程序和成员名单。

4. INVESTIGATOR 研究者

4.1 Investigator's Qualifications and Agreements 研究者的资格和协议

4.1.1 The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority(ies).

研究者应当在受教育、培训和经验方面有资格承担实施试验的责任，应当符合适用的管理要求所说明的所有条件，并应当通过现时的个人简历/或申办者、IRB/IEC 和/或管理当局要求的其他相关文件提供这种资格证明。

4.1.2 The investigator should be thoroughly familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current Investigator's Brochure, in the product information and in other information sources provided by the sponsor.

研究者应当充分熟悉在试验方案、研究者手册、产品自料以及申办者提供的其他资料中所述的试验用药品的合适用途。

4.1.3 The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.

研究者应当了解并遵循ＧＣＰ和适用的管理要求。

4.1.4 The investigator/institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies).

研究者/研究机构应当允许申办者的监察和稽查，以及管理部门的视察。

4.1.5 The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

研究者应当有一份合适资格、并已委派给他们与试验相关的和总要任务的人员名单。

4.2 Adequate Resources 足够的资源

4.2.1 The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.

研究者应能证明（如根据遗忘的数据）在协议的招募期内接纳所需要数目的合适对象的可能性。

4.2.2 The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.

研究者在协议的试验期内应当有足够的时间实施和完成试验。

4.2.3 The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

在可预见的试验期内，研究者应当有足够数量的合格职员和充足的设备来争取、安全的实施试验。

4.2.4 The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

研究者应当保证所有的试验辅助人员已充等了解试验方案，试验用药品，及他们与试验相关的责任和职能。

4.3 Medical Care of Trial Subjects 试验对象的医疗

4.3.1 A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, should be responsible for all trial-related medical (or dental) decisions.

作为一名研究者或次级研究人员的合格医生（或牙医）应当对与试验有关的所有医学（牙科）决定负责。

4.3.2 During and following a subject's participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a subject for any adverse events, including clinically significant

laboratory values, related to the trial. The investigator/institution should inform a subject when medical care is needed for intercurrent illness(es) of which the investigator becomes aware.

在对象参加一个试验期间或以后，研究者/研究机构应当保证为对象的任何不良反应，包括与试验有关的临床上有意义的实验室测定值提供合宜的医疗保健。研究者知道并发疾病需要医疗保健时，研究者/研究机构应当通知对象。

4.3.3 It is recommended that the investigator inform the subject's primary physician about the subject's participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.

如果对象有初级医生并且对象同意让初级医生知道，建议研究者将对象参加试验的事通知对象的初级医生。

4.3.4 Although a subject is not obliged to give his/her reason(s) for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the subject's rights.

尽管一名对象没有义务给出他/她中途退出试验的理由，研究者仍应当在充分尊重对象权利的同时作出合理的努力确认其退出理由。

4.4 Communication with IRB/IEC 与 IRB/IEC 的交流

4.4.1 Before initiating a trial, the investigator/institution should have written and dated approval/favourable opinion from the IRB/IEC for the trial protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to subjects.

在开始一个试验前，研究者/研究机构应当有 IRB/IEC 对试验方案、知情同意书、知情同意书的更新、对象招募程序（如广告）、以及提供给对象的任何其他书面资料的书面的、注明日期的批准/赞成意见。

4.4.2 As part of the investigator's/institution's written application to the IRB/IEC, the investigator/institution should provide the IRB/IEC with a current copy of the Investigator's Brochure. If the Investigator's Brochure is updated during the trial, the investigator/institution should supply a copy of the updated Investigator's Brochure to the IRB/IEC.

作为研究者/研究机构向 IRB/IEC 书面申请的一部分，研究者/研究机构应当向 IRB/IEC 提供研究者手册的当前文本。如果研究者手册在试验中更新，研究者/研究机构应当向 IRB/IEC 提供更新的研究者手册。

4.4.3 During the trial the investigator/institution should provide to the IRB/IEC all documents subject to review.

在试验期间，研究者/研究机构应当向 IRB/IEC 提供全部供审评的文件。

4.5 Compliance with Protocol 对试验方案的依从性

4.5.1 The investigator/institution should conduct the trial in compliance with the protocol agreed to by the

sponsor and, if required, by the regulatory authority(ies) and which was given approval/favourable opinion by the IRB/IEC. The investigator/institution and the sponsor should sign the protocol, or an alternative contract, to confirm agreement.

研究者/研究机构应当按照申办者和（如有必要）管理当局同意、并得到 IRB/IEC 批准/赞成的方案实施试验。研究者/研究机构和申办者应当在方案上或另立的合同上签字，确认同意方案。

4.5.2 The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favourable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change in monitor(s), change of telephone number(s)).

研究者在没有取得申办者同意和事先得到 IRB/IEC 对于一个修改的审评与书面批准/赞成时，不应当偏离或改变方案，除非必需消除试验对象的直接危险或这些改变只涉及试验的供应或管理方面（如更换监察员，改变电话号码）。

4.5.3 The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol.

研究者，或由研究者指定的人，应当记录和解释已批准方案的任何偏离。

4.5.4 The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior IRB/IEC approval/favourable opinion. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be submitted:

为了消除对试验对象的直接危险，研究者可以没有 IRB/IEC 的预先批准/赞成意见偏离或改变方案。所实施的偏离或改变、改变的理由、以及所提议的方案修改尽可能地提交给：

a) to the IRB/IEC for review and approval/favourable opinion,

IRB/IEC 审评并得到批准/赞成

b) to the sponsor for agreement and, if required,

申办者征得同意和，如果需要

c) to the regulatory authority(ies).

管理当局

4.6 Investigational Product(s) 试验药品

4.6.1 Responsibility for investigational product(s) accountability at the trial site(s) rests with the investigator/institution.

在试验单位，试验用药品计数地责任归于研究者/研究机构。

4.6.2 Where allowed/required, the investigator/institution may/should assign some or all of the investigator's/institution's duties for investigational product(s) accountability at the trial site(s) to an appropriate pharmacist or another appropriate individual who is under the supervision of the

investigator/institution..

只要允许/需要，研究者/研究机构可以/应当将试验单位研究者地/机构对试验用药品计数的责任部分或全部指派给在研究者/研究机构监督下的合适的药师或其他适当的人员。

4.6.3 The investigator/institution and/or a pharmacist or other appropriate individual, who is designated by the investigator/institution, should maintain records of the product's delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product(s). These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product(s) and trial subjects. Investigators should maintain records that document adequately that the subjects were provided the doses specified by the protocol and reconcile all investigational product(s) received from the sponsor.

研究者/研究机构和/或受研究者/研究机构指派的一名药师或其他合适的个人，应当保 存试验用药品交到试验单位的记录，在试验单位的存货清单，每位对象的使用记录，和未使 用的药品交还给申办者或另法处置的记录。这些记录应包含日期、数量、批号/系列号、时效期（如有）、和分配给试验用药品和试验对象的特别编码。研究者应保持记载有按方案说 明给予对象药量的记录，并应与从申办者处收到的试验用药品总数一致。

4.6.4 The investigational product(s) should be stored as specified by the sponsor (see 5.13.2 and 5.14.3) and in accordance with applicable regulatory requirement(s).

试验用药品应按申办者的说明储存（见 5.13.2 和 5.14.3）并符合适用的管理要求。

4.6.5 The investigator should ensure that the investigational product(s) are used only in accordance with the approved protocol.

研究者应当保证试验用药品只按已批准的方案使用。

4.6.6 The investigator, or a person designated by the investigator/institution, should explain the correct use of the investigational product(s) to each subject and should check, at intervals appropriate for the trial, that each subject is following the instructions properly.

研究者或研究者/研究机构指定的人，应当向每一位对象解释试验用药品的娥正确用法，并应在适合于该试验的一定间隔检查每一位对象完全遵照使用说明用药。

4.7 Randomization Procedures and Unblinding 随机程序和揭盲

The investigator should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product(s).

研究者应当遵循试验的随机化程序（如果有），并应保证依照方案打开随机号码。如果试验采用盲法，研究者应当立即记录并向申办者解释试验用药品的任何提前破盲（如以外破盲，因严重不良事件破盲）。

4.8 Informed Consent of Trial Subjects 试验对象的知情同意

4.8.1 In obtaining and documenting informed consent, the investigator should comply with the applicable

regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. Prior to the beginning of the trial, the investigator should have the IRB/IEC's written approval/favourable opinion of the written informed consent form and any other written information to be provided to subjects.

在获得和证明知情同意过程中，研究者应当遵循适用的管理规定，应当符合ＧＣＰ和源自赫尔辛基年宣言的伦理原则。在开始试验前，研究者应当有 IRB/IEC 对于书面的知情同意书和提供给对象的其他文字资料的书面批准/赞成意见。

4.8.2 The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject's consent. Any revised written informed consent form, and written information should receive the IRB/IEC's approval/favourable opinion in advance of use. The subject or the subject's legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the trial. The communication of this information should be documented.

无论何时得到与对象的知情同意可能相关的新的资料后，提供给对象的书面知情同意书和其他文字资料都应当进行修改。修改后的书面知情同意书和其他文字资料在适用前都应当得到 IRB/IEC 的批准/赞成。如果有与对象继续参加试验的愿望可能相关的新资料，应及时通知对象和对象的合法可接受代表。这种资料的交流应当被记录下来。

4.8.3 Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.

无论试验就人员还是试验职员，都不应强迫或不正当地影响一个对象参加或继续参加一个试验。

4.8.4 None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.

关于试验的口述或书面的资料，包括书面的知情同意书，都不应包含会引起对象或对象的合法可接受代表放弃或看来象是放弃任何合法利益的语言；或者免除或看来象是免除研究者、机构、申办者或他们的代理由于疏忽应负责任的语言。

4.8.5 The investigator, or a person designated by the investigator, should fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the trial including the written information and the approval/ favourable opinion by the IRB/IEC.

研究者或由研究者指定的人，至少应当告诉对象，或如果对象不能提供知情同意时告诉对象的合法可接受的代表，所有与试验相关的方面，包括文字资料和 IRB/IEC 的批准/赞成意见。

4.8.6 The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable.

关于试验的口述和书面资料，包括书面知情同意书，所用的语言应当是非技术术语性的实用语言，

对于对象或对象的合法可接受代表或公正的见证人应当是易懂的。

4.8.7 Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or the subject's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legally acceptable representative.

在可能得到知情同意之前，研究者或研究者指定的人应当让对象或对象的合法接受代表有充足的时间和机会询问关于试验的详细情况和决定是否参加试验。应当回答所有问题，让对象或对象的合法可接受代表满意。

4.8.8 Prior to a subject’s participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.

在对象参加试验之前，对象或对象的合法可接受代表以及执行知情同意讨论的人应亲自前述知情同意书并注明日期。

4.8.9 If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects, is read and explained to the subject or the subject’s legally acceptable representative, and after the subject or the subject’s legally acceptable representative has orally consented to the subject’s participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject’s legally acceptable representative.

如果一名对象不能阅读，或一位合法可接受的代表不能阅读，在整个知情同意讨论期间必需有一位合法可接受的代表不能在书面的知情同意书和其他文件资料交给对象后，向对象或对象的合法可接受代表进行阅读并解释，在对象或对象的合法可接受代表已经口头同意对象参加试验、并且如果可能已在知情同意书上签字并注明日期。见证人通过签署知情同意书证明，知情同意书和其他文字资料已被准确的向对象或对象的合法可接受代表作了解释，对象或对象的合法可接受代表显然懂得这些解释，知情同意是对象或对象的合法可接受代表自由的给出的。

4.8.10 Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:

知情同意讨论和提供给对象的书面的知情同意书以及其他文字资料应当包括以下问题的解释：

a) That the trial involves research.

试验涉及的研究

b) The purpose of the trial.

试验目的

c) The trial treatment(s) and the probability for random assignment to each treatment.

试验治疗和随机分配到各种治疗的可能性

d) The trial procedures to be followed, including all invasive procedures.

试验就行的程序，包括所有侵袭性程序

e) The subject's responsibilities.

对象的责任

f) Those aspects of the trial that are experimental.

试验的实验方面性

g) The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.

带给对象、可能时带给胚胎、胎儿或哺乳婴儿的合理预见的危险或不方便。

h) The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.

可合理预见的受益。不存在预期的临床受益时，对象应当知道这一点。

i) The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.

对象可能得到的可替代治疗程序或过程，以及这些治疗的重要潜在受益和风险。

j) The compensation and/or treatment available to the subject in the event of trial-related injury.

在与试验相关的伤害事件中对象可获得的补偿和/治疗。

k) The anticipated prorated payment, if any, to the subject for participating in the trial.

给参加试验对象的预期按比例分配的支付（如果有）

l) The anticipated expenses, if any, to the subject for participating in the trial.

对象因参加试验的预期花费（如果有）

m) That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

对象参加试验是自愿的，对象可以拒绝参加试验，或在任何时候退出试验而不会收到出发或损失本来对象有权利得到的利益。

n) That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.

监察员、稽查员、IRB/IEC 和管理当局将被准予在不违反对象的保密性、在适用法律与规定准许

的程度直接访问对象的原始医学记录以查证临床试验程序和/或数据，对象或对象的合法可接受的代表通过签署书面的知情同意书授权这种访问。

o) That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.

在适用法律和/或规定允许的范围，能鉴别对象的记录应保密，不得公开这些记录。如果试验结果发表，对象鉴别仍然是保密的。

p) That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.

如果得到与对象继续参加试验的愿望可能相关的资料，对象或对象的合法可接受代表将得到及时通报。

q) The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.

需要进一步了解有关试验资料和试验对象的权利时的联系人，以及在发生与试验有关的伤害时的联系人。

r) The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.

对象参加试验可能被终止的可预见情况和/或理由

s) The expected duration of the subject's participation in the trial.

对象参加试验的预期持续时间

t) The approximate number of subjects involved in the trial.

参加试验对象的大约人数

4.8.11 Prior to participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject's participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to subjects.

在参加试验前，对象或对象的合法可接受代表应收到一份已签署并注明日期的书面知情同意书的复印件和其他提供给对象的书面资料。对象参加试验期间，对象或对象的合法可接受代表应收到已签署并注明日期的知情同意书的更新的复印件和提供给对象的书面资料的修改文本。

4.8.12 When a clinical trial (therapeutic or non-therapeutic) includes subjects who can only be enrolled in the trial with the consent of the subject's legally acceptable representative (e.g., minors, or patients with severe dementia), the subject should be informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should sign and personally date the written informed consent.

当一个临床试验（治疗的或非治疗的）包括那些职能由其合法可接受代表表示进入试验的对象时（如未成年人，或严重痴呆病人），应当在对象能理解的程度告知对象关于试验的信息。如果可能，对象应当亲自签署书面的知情同意并注明日期。

4.8.13 Except as described in 4.8.14, a non-therapeutic trial (i.e. a trial in which there is no anticipated direct clinical benefit to the subject), should be conducted in subjects who personally give consent and who sign and date the written informed consent form.

除非如 4.8.14 所描述的情况外，一个非治疗试验（如对于对象没有可预期的直接临床好处的试验）应当在那些亲自同意并在书面的知情同意书上签字和注明日期的对象中进行。

4.8.14 Non-therapeutic trials may be conducted in subjects with consent of a legally acceptable representative provided the following conditions are fulfilled:

只要符合下列条件，非治疗试验可以在由合法可接受代表同意的对象中进行：

a) The objectives of the trial can not be met by means of a trial in subjects who can give informed consent personally.

试验的目的不能通过在能亲自给出知情同意的对象中进行的试验达到。

b) The foreseeable risks to the subjects are low.

对象的可预见风险很低

c) The negative impact on the subject's well-being is minimized and low.

对于对象健康的负面影响被减到最小，并且是最低的

d) The trial is not prohibited by law.

法律不禁止该试验

e) The approval/favourable opinion of the IRB/IEC is expressly sought on the inclusion of such subjects, and the written approval/ favourable opinion covers this aspect.

明确的寻求 IRB/IEC 对接纳这些对象的批准/赞成意见；书面的批准/赞成意见同意接纳这些对象。

Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Subjects in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

除非被证明是一个例外，这类试验应当在具有预期适用试验用药品的疾病或状况的病人中进行。这些试验中对象应当受到特别的密切检查，如果他们显得过分痛苦，应当退出试验。

4.8.15 In emergency situations, when prior consent of the subject is not possible, the consent of the subject's legally acceptable representative, if present, should be requested. When prior consent of the subject is not possible, and the subject's legally acceptable representative is not available, enrolment of the subject should require measures described in the protocol and/or elsewhere, with documented approval/favourable opinion by the IRB/IEC, to protect the rights, safety and well-being of the subject and to ensure compliance with applicable regulatory requirements. The subject or the subject's legally acceptable representative should be informed about the trial as soon as possible and consent to continue and other consent as appropriate (see 4.8.10) should be requested.

在紧急情况下，不可能事先得到对象的知情同意时，应该请求对象的合法可接受代表（如果在场）的同意。当对象的接纳需要按方案和/或其他文件中描述的、得到 IRB/IEC 的书面批 准/赞成意见的方法进行，以保护对象的权利、安全和健康，并保证依从适用的管理要求。应尽可能地通知对象或对象地合法可接受代表关于试验地事，并应得到他们继续参加试验和 其他事项（见 4.8.10）的知情同意。

4.9 Records and Reports 记录和报告

4.9.1 The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports.

研究者应当保证给申办者的病历报告表（ＣＲＦ）和所有需要的报告中的数据的准确性、完整性、易辩性和及时性。

4.9.2 Data reported on the CRF, that are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.

ＣＲＦ中来自源文件的数据应当与源文件一致，如由不一致应作出解释。

4.9.3 Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e. an audit trail should be maintained); this applies to both written and electronic changes or corrections (see 5.18.4 (n)). Sponsors should provide guidance to investigators and/or the investigators' designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRFs made by sponsor's designated representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections.

ＣＲＦ中数据的任何改变或变更，应当注明日期、姓名首字母和说明（如有必要），并应当使原来的记录依然可见（即应保留核查痕迹）；这同样适用于文字和电子的改变或更正（见 5.18.4（ｎ））。申办者应当向研究者和/或研究者指定的代表提供关于进行这种更正的指南。申办者应当有书面的程序以保证在 CRF 中由申办者指定的代表作出的改变或更正是有记录的、有必要的，并得到研究者的认可。研究者应当保留改变和更正的记录。

4.9.4 The investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial (see 8.) and as required by the applicable regulatory requirement(s). The investigator/institution should take measures to prevent accidental or premature destruction of these documents.

研究者/研究机构应当按《实施临床试验的基本文件》（见 8.）所述和适用管理要求保存试验文件。研究者/研究机构应当采取措施防止这些文件的以外或过早破坏。

4.9.5 Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained (see 5.5.12).

基本文件应当保留到最后批准在一个ＩＣＨ地区上市后至少 2 年，和直到最后在一个ＩＣＨ地区没有未决的或仍在考虑的上市应用，或试验用药品的临床研究正式停止后至少已过去 2 年。但是，如果适用的管理要求需要或申办者签署的协议需要，这些文件应当被保存更长时间。申办者有责任统制研究者/研究机构，到什么时候这些文件不必再保存（见 5.5.12）

4.9.6 The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.

试验的财务方面事宜应在申办者与研究者/研究机构的协议书中说明。

4.9.7 Upon request of the monitor, auditor, IRB/IEC, or regulatory authority, the investigator/institution should make available for direct access all requested trial-related records.

根据监察员、稽查员、IRB/IEC 或管理当局的要求，研究者/研究机构应当提供他们查阅所需的与试验有关的全部记录。

4.10 Progress Reports 进展报告

4.10.1 The investigator should submit written summaries of the trial status to the IRB/IEC annually, or more frequently, if requested by the IRB/IEC.

研究者应当每年一次，或应 IRB/IEC 要求的频度向 IRB/IEC 提交书面的试验情况摘要。

4.10.2 The investigator should promptly provide written reports to the sponsor, the IRB/IEC (see 3.3.8) and, where applicable, the institution on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects.

研究者应当迅速向申办者、IRB/IEC（见 3.3.8）和（如果合适）向研究机构提供关于明显影响试验实施和/或增加对象风险的任何改变的书面报告。

4.11 Safety Reporting 安全性报告

4.11.1 All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the trial subjects rather than by the subjects' names, personal identification numbers, and/or addresses. The investigator should also comply with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the regulatory authority(ies) and the IRB/IEC.

除了试验方案或其他文件（如研究者手册）认为不必即时报告的那些严重不良事件（ＳＡＥ）以外，所有ＳＡＥ都应当立即向申办者报告。即时报告应理解为迅速的详细书面报告。即时和随访报告中的对象鉴别应当采用采用指定给试验对象的独特号码，而不是对象姓名、个人身份号码和/或地址。研究者还应当服从关于管理当局和 IRB/IEC 报告非预期的药物严重不良反应的适用管理要求。

4.11.2 Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.

在试验方案中被确定为对安全性评价是关键的不良事件和/或实验室异常应当按照报告要求和申办者在方案中说明的时限内向申办者报告。

4.11.3 For reported deaths, the investigator should supply the sponsor and the IRB/IEC with any additional requested information (e.g., autopsy reports and terminal medical reports).

对于所报告的死亡事件，研究者应当向申办者和 IRB/IEC 提供所需要的全部附加资料（如解剖报告和最终医学报告）。

4.12 Premature Termination or Suspension of a Trial 试验中止或暂停

If the trial is prematurely terminated or suspended for any reason, the investigator/institution should promptly inform the trial subjects, should assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirement(s), should inform the regulatory authority(ies). In addition:

如果一个试验因为任何理由过早的停止或暂停，研究者/研究机构应当迅速通知试验对象，应当保证对象的合适治疗和随访，和根据适用的管理要求应当通知管理当局。另外：

4.12.1If the investigator terminates or suspends a trial without prior agreement of the sponsor, the investigator should inform the institution where applicable, and the investigator/institution should promptly inform the sponsor and the IRB/IEC, and should provide the sponsor and the IRB/IEC a detailed written explanation of the termination or suspension.

如果研究者未与申办者事先协议便中止或暂停一个试验，研究者应当通知研究机构，研究者/研究机构应当立即通知申办者和 IRB/IEC 提供中止或暂停试验的详细书面解释。

4.12.2If the sponsor terminates or suspends a trial (see 5.21), the investigator should promptly inform the institution where applicable and the investigator/institution should promptly inform the IRB/IEC and provide the IRB/IEC a detailed written explanation of the termination or suspension.

如果申办者中止或暂停一个试验（见 5.21），研究者应当立即通知研究机构，研究者/研究机构应立即通知 IRB/IEC 并向 IRB/IEC 提供中止和暂停的详细书面解释。

4.12.3If the IRB/IEC terminates or suspends its approval/favourable opinion of a trial (see 3.1.2 and 3.3.9), the investigator should inform the institution where applicable and the investigator/institution should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension.

如果 IRB/IEC 终止或暂停它对一个试验的批准/赞成意见（见 3.12 和 3.3.9），研究者应当通知研究机构，研究者/研究机构应当立即通报申办者并提供终止或暂停的详细书面解释。

4.13 Final Report(s) by Investigator 研究者的最终报告

Upon completion of the trial, the investigator, where applicable, should inform the institution; the investigator/institution should provide the IRB/IEC with a summary of the trial's outcome, and the regulatory authority(ies) with any reports required.

在试验完成后，研究者应当通知研究机构，研究者/研究机构应当向 IRB/IEC 提供试验结果的摘要，向管理当局提供所需要的所有报告。

5. SPONSOR 申办者

5.1 Quality Assurance and Quality Control 质量保证和质量控制

5.1.1 The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).

申办者负责按照书面ＳＯＰ执行和维持质量保证和质量控制系统，保证试验的实施和数据的产生、记录和报告询询试验方案、ＧＣＰ、及适用的管理要求。

5.1.2 The sponsor is responsible for securing agreement from all involved parties to ensure direct access (see 1.21) to all trial related sites, source data/documents , and reports for the purpose of monitoring and auditing by the sponsor, and inspection by domestic and foreign regulatory authorities.

申办者有责任保护各有关方面的协议，保证申办者以检查和稽查为目的的直接访问（见 1.21）各有关试验单位、源数据/文件、报告，以及保证国内和国外管理当局的视察。

5.1.3 Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.

在数据处理的每一阶段都应当有质量控制，以保证所有的数据是可靠的并已经得到正确处理。

5.1.4 Agreements, made by the sponsor with the investigator/institution and any other parties involved with the clinical trial, should be in writing, as part of the protocol or in a separate agreement.

申办者和研究者/研究机构以及参加临床试验的其他方应当订立书面协议；协议可以是方案的一部分，也可以上单独的协议。

5.2 Contract Research Organization (CRO) 合同研究组织

5.2.1 A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The CRO should implement quality assurance and quality control.

申办者可以将与试验有关的责任和任务部分或全部转移给一个ＣＲＯ，但是试验数据的质量和完整性的最终责任永远在申办者。ＣＲＯ应当建立质量保证和质量控制。

5.2.2 Any trial-related duty and function that is transferred to and assumed by a CRO should be specified in writing.

转移给ＣＲＯ的或ＣＲＯ承担的任何与试验有关的责任和职能应当有书面说明。

5.2.3 Any trial-related duties and functions not specifically transferred to and assumed by a CRO are retained by the sponsor.

没有明确转移给ＣＲＯ或由ＣＲＯ承担的任何与试验有关责任和职能仍然由申办者承担。

5.2.4 All references to a sponsor in this guideline also apply to a CRO to the extent that a CRO has assumed the trial related duties and functions of a sponsor.

本指导原则中涉及申办者的一切也适用于一个ＣＲＯ，就像ＣＲＯ已经承担了一个申办者的与试验相关责任和职能。

5.3 Medical Expertise 医学专家

The sponsor should designate appropriately qualified medical personnel who will be readily available to advise on trial related medical questions or problems. If necessary, outside consultant(s) may be appointed for this purpose.

申办者应当指定有合适资格的医学人员，他们能迅速对试验有关疑问或问题提出建议。如果必要，可以人民外来顾问。

5.4 Trial Design 试验设计

5.4.1 The sponsor should utilize qualified individuals (e.g. biostatisticians, clinical harmacologists, and physicians) as appropriate, throughout all stages of the trial process, from designing the protocol and CRFs and planning the analyses to analyzing and preparing interim and final clinical trial reports.

在试验过程的各个阶段，从设计试验方案、ＣＲＦ、计划分析到分析和准备中期与最终临床试验报告，申办者应当任用有合适资格的人（如生物统计学专家，临床药理学家和医生）。

5.4.2 For further guidance: Clinical Trial Protocol and Protocol Amendment(s) (see 6.), the ICH Guideline for Structure and Content of Clinical Study Reports, and other appropriate ICH guidance on trial design, protocol and conduct.

进一步的指导原则：《临床试验方案和方案修改》（见 6.），《ＩＣＨ临床试验报告的结构　和内容指导原则》和关于试验设计、方案和执行的其他ＩＣＨ指导原则。

5.5 Trial Management, Data Handling, and Record Keeping

试验管理、数据处理与记录保存

5.5.1 The sponsor should utilize appropriately qualified individuals to supervise the overall conduct of the trial, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports.

申办者应当任用有合适资格的人监督试验的全面实施、处理数据、核对数据，进行统计分析和准备试验报告。

5.5.2 The sponsor may consider establishing an independent data-monitoring committee (IDMC) to assess the progress of a clinical trial, including the safety data and the critical efficacy endpoints at intervals, and to recommend to the sponsor whether to continue, modify, or stop a trial. The IDMC should have written operating procedures and maintain written records of all its meetings.

申办者应考虑建立一个独立的数据监察委员会（ＩＤＭＣ），定期评价临床试验的　进展、修改或停

止试验。ＩＤＭＣ应当有书面的操作程序并保存它所有的会议记录。

5.5.3 When using electronic trial data handling and/or remote electronic trial data systems, the sponsor should:

应用电子试验数据处理和/或遥控电子试验数据系统时，申办者应当：

a) Ensure and document that the electronic data processing system(s) conforms to the sponsor's established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation).

确保并证明电子数据处理系统符合申办者所设定的关于完整性、准确性、可靠性和一致期望的性能（如数据确认）的要求。

b) Maintains SOPs for using these systems.

保持使用这些系统的 SOP

c) Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (i.e. maintain an audit trail, data trail, edit trail).

保证系统的设计允许数据修改按如下方式进行：数据的改变被记录下来而不删除已经录入的数据（即保留稽查痕迹、数据痕迹和编辑痕迹）

d) Maintain a security system that prevents unauthorized access to the data.

有一个防止未经授权人员访问数据的安全体系

e) Maintain a list of the individuals who are authorized to make data changes (see 4.1.5 and 4.9.3).

有一份被授权修改数据的人员名单（见 4.1.5 和 4.9.3）

f) Maintain adequate backup of the data.

足够的数据备份

g) Safeguard the blinding, if any (e.g. maintain the blinding during data entry and processing).

如采用盲法，保护盲法安全（在数据输入和处理期间维持盲法）

5.5.4 If data are transformed during processing, it should always be possible to compare the original data and observations with the processed data.

如果再处理中数据作了转换，将原始数据和观测值与处理后得数据进行比较。

5.5.5 The sponsor should use an unambiguous subject identification code (see 1.58) that allows identification of all the data reported for each subject.

申办者应当使用明确得对象识别码（见 1.58），以鉴别所报告得每一位对象得所有数据。

5.5.6 The sponsor, or other owners of the data, should retain all of the sponsor-specific essential documents pertaining to the trial (see 8. Essential Documents for the Conduct of a Clinical Trial).

申办者或数据得其他拥有者应当保留申办者当得有关试验得所有基本文件（见 8.实施临床试验得基本文件）。

5.5.7 The sponsor should retain all sponsor-specific essential documents in conformance with the applicable regulatory requirement(s) of the country(ies) where the product is approved, and/or where the sponsor intends to apply for approval(s).

申办者应当保留所有申办者方的、与产品被批准和/或申办者打算申请批准的国家适用管理要求一致的基本文件。

5.5.8 If the sponsor discontinues the clinical development of an investigational product (i.e. for any or all indications, routes of administration, or dosage forms), the sponsor should maintain all sponsor-specific essential documents for at least 2 years after formal discontinuation or in conformance with the applicable regulatory requirement(s).

如果申办者停止一个试验用药品的临床研究（如某个或所有适应证，给药途径，或剂型），申办者应当保留所有申办者方的基本文件至正式停止后至少 2 年，或与适用管理规定一致。

5.5.9 If the sponsor discontinues the clinical development of an investigational product, the sponsor should notify all the trial investigators/institutions and all the regulatory authorities.

如果申办者停止一个试验用药品的临床研究，申办者应当通报所有研究者/研究机构和所有管理部门。

5.5.10 Any transfer of ownership of the data should be reported to the appropriate authority(ies), as required by the applicable regulatory requirement(s).

任何数据所有权的转让应依照现行管理法规的要求想所属的管理当局报告

5.5.11 The sponsor specific essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirement(s) or if needed by the sponsor.

申办者方的基本文件应当被保留到最后批准在一个ＩＣＨ地区上市应用后至少 2 年，和直至在一个ＩＣＨ地区没有未决的或仍在考虑的上市应用，或试验用药品的临床研究正式停止后已过去至少 2 年。但如果适用管理要求需要或申办者要求，这些文件应当被保留更长时间。

5.5.12 The sponsor should inform the investigator(s)/institution(s) in writing of the need for record retention and should notify the investigator(s)/institution(s) in writing when the trial related records are no longer needed.

申办者应当以书面通知研究者/研究机构关于记录保存得要求，当试验相关记录不再需要时应书面通报研究者/研究机构。

5.6 Investigator Selection 研究者选择

5.6.1 The sponsor is responsible for selecting the investigator(s)/institution(s). Each investigator should be qualified by training and experience and should have adequate resources (see 4.1, 4.2) to properly

conduct the trial for which the investigator is selected. If organization of a coordinating committee and/or selection of coordinating investigator(s) are to be utilized in multicentre trials, their organization and/or selection are the sponsor's responsibility.

申办者有责任选择研究者/研究机构。每一个研究者应当时通过培训合格的和有经验的，应当有足够的自愿（见 4.1，4.2）正确的实施其被选择来进行的试验。如果在多中心试验中将组织一个协调委员会组织和/或选择协调研究者，他们的组织和/或选择是申办者的责任。

5.6.2 Before entering an agreement with an investigator/institution to conduct a trial, the sponsor should provide the investigator(s)/institution(s) with the protocol and an up-to-date Investigator's Brochure, and should provide sufficient time for the investigator/institution to review the protocol and the information provided.

在与研究者/研究机构签署一个进行试验的协议之前，申办者应当向研究者/研究机构提供试验方按和最新的研究者手册，并应当提供足够的时间让研究者/研究机构去审议方按和所提供的资料。

5.6.3 The sponsor should obtain the investigator's/institution's agreement:

申办者应获得研究者或研究机构的同意

a) to conduct the trial in compliance with GCP, with the applicable regulatory requirement(s) (see 4.1.3), and with the protocol agreed to by the sponsor and given pproval/favourable opinion by the IRB/IEC (see 4.5.1);

按照ＧＣＰ、适用管理要求（见 4.1.3）和经申办者同意、IRB/IEC 批准/赞成（见 4.5.1）和方按实施临床试验。

b) to comply with procedures for data recording/reporting;

遵循数据记录/报告程序

c) to permit monitoring, auditing and inspection (see 4.1.4) and

运行监查、稽查及视察

d) to retain the trial related essential documents until the sponsor informs the investigator/ institution these documents are no longer needed (see 4.9.4 and 5.5.12).

允许保留与试验有关的基本文件直至申办者通知研究者/研究机构这些文件不再需要为止（见 4.9.4 和 5.5.12）

The sponsor and the investigator/institution should sign the protocol, or an alternative document, to confirm this agreement.

在开始一个试验前，申办者应当定义、规定和分配与试验相关的责任和职能。

5.7 Allocation of Responsibilities　职责的分配

Prior to initiating a trial, the sponsor should define, establish, and allocate all trial-related duties and functions.

在开始一个试验前，申办者应当定义、规定和分配与试验相关的责任和职能。

5.8 Compensation to Subjects and Investigators 对受试者、研究者的补偿

5.8.1 If required by the applicable regulatory requirement(s), the sponsor should provide insurance or should indemnify (legal and financial coverage) the investigator/the institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence.

如果适用管理要求需要，申办者应当提供保险或应当补偿（法律和财政的范围）研究者/研究机构因试验而提出的要求，但因治疗不当和/或过失所致的除外。

5.8.2 The sponsor's policies and procedures should address the costs of treatment of trial subjects in the event of trial-related injuries in accordance with the applicable regulatory requirement(s).

申办者的保险单和程序应当说明符合适用管理要求的与试验相关的伤害事件中试验对象治疗的费用。

5.8.3 When trial subjects receive compensation, the method and manner of compensation should comply with applicable regulatory requirement(s).

试验对象收到补偿时，补偿的方法和方式应当符合适用管理要求。

5.9 Financing 财务

The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.

试验的财务方面内容应当列入申办者和研究者/研究机构之间的协议中。

5.10 Notification/Submission to Regulatory Authority(ies) 向管理当局通知或申报

Before initiating the clinical trial(s), the sponsor (or the sponsor and the investigator, if required by the applicable regulatory requirement(s)) should submit any required application(s) to the appropriate authority(ies) for review, acceptance, and/or permission (as required by the applicable regulatory requirement(s)) to begin the trial(s). Any notification/submission should be dated and contain sufficient information to identify the protocol.

在开始临床试验前，申办者（或适用管理要求需要，申办者和研究者）应当向相应的管理部门提交所需要的申请表，供审评、接受和/或许可（如适用管理要求需要）开始试验。通报/提交的资料应当注明日期，并包括足够鉴定试验方按的资料。

5.11 Confirmation of Review by IRB/IEC IRB/IEC 的评审和确认

5.11.1 The sponsor should obtain from the investigator/institution:

申办者应当从研究者/研究机构方得到：

a) The name and address of the investigator's/institution's IRB/IEC.

研究者/研究机构方的 IRB/IEC 成员的姓名和地址

b) A statement obtained from the IRB/IEC that it is organized and operates according to GCP and the applicable laws and regulations.

IRB/IEC 关于其组织和操作符合ＧＣＰ和适用法律法规的陈述

c) Documented IRB/IEC approval/favourable opinion and, if requested by the sponsor, a current copy of protocol, written informed consent form(s) and any other written information to be provided to subjects, subject recruiting procedures, and documents related to payments and compensation available to the subjects, and any other documents that the IRB/IEC may have requested.

书面的 IRB/IEC 批准/赞成；如果申办者要求，最新的试验方按、书面知情同意书和其他将提供给对象书面资料的复印件，对象接纳程序，和给予对象的支付和补偿的有关文件，以及 IRB/IEC 所要的其他文件。

5.11.2 If the IRB/IEC conditions its approval/favourable opinion upon change(s) in any aspect of the trial, such as modification(s) of the protocol, written informed consent form and any other written information to be provided to subjects, and/or other procedures, the sponsor should obtain from the investigator/institution a copy of the modification(s) made and the date approval/favourable opinion was given by the IRB/IEC.

如果 IRB/IEC 以修改试验的某个方面作为批准/赞成的条件，如修改方按，书面的知情同意书和其他提供给对象和/或其他程序的书面资料，申办者应当从研究者/研究机构得到已作出修改的副本和 IRB/IEC 给出批准/赞成日期。

5.11.3 The sponsor should obtain from the investigator/institution documentation and dates of any IRB/IEC reapprovals/re-evaluations with favourable opinion, and of any withdrawals or suspensions of approval/favourable opinion.

申办者应当从研究者/研究机构得到所有 IRB/IEC 给出赞成意见的再批准/再评价，以及撤销或暂停批准/赞成的文件和日期。

5.12 Information on Investigational Product(s) 有关试验药品的信息

5.12.1 When planning trials, the sponsor should ensure that sufficient safety and efficacy data from nonclinical studies and/or clinical trials are available to support human exposure by the route, at the dosages, for the duration, and in the trial population to be studied.

计划试验时，申办者应当保证有足够的非临床研究和/或临床研究的安全性和有效性数据支持所研究的试验人群暴露的给药途径、剂量和持续时间。

5.12.2 The sponsor should update the Investigator's Brochure as significant new information becomes available (see 7. Investigator's Brochure).

当有重要的新资料时，申办者应当更新研究者手册（见 7.研究者手册）。

5.13 Manufacturing, Packaging, Labelling, and Coding Investigational Product(s) 试验药品生产、包装、标签和编码

5.13.1 The sponsor should ensure that the investigational product(s) (including active comparator(s) and

placebo, if applicable) is characterized as appropriate to the stage of development of the product(s), is manufactured in accordance with any applicable GMP, and is coded and labelled in a manner that protects the blinding, if applicable. In addition, the labelling should comply with applicable regulatory requirement(s).

申办者应当保证试验用药品（包括活性对照品和安慰剂）具有适合产品开发阶段的特性，按照适用的ＧＭＰ生产、编码和标签的方式应适合于保护盲法。此外，标签应当符合适用管理要求。

5.13.2 The sponsor should determine, for the investigational product(s), acceptable storage temperatures, storage conditions (e.g. protection from light), storage times, reconstitution fluids and procedures, and devices for product infusion, if any. The sponsor should inform all involved parties (e.g. monitors, investigators, pharmacists, storage managers) of these determinations.

申办者应当确定试验用药品的允许储存温度、储存条件（如避光）、储存时间、重组溶液和程序，以及必要时药物的输注装置。申办者应当将这些决定通知所有有关各方（如监察员、研究者、药师、储存管理人员）。

5.13.3 The investigational product(s) should be packaged to prevent contamination and unacceptable deterioration during transport and storage.

试验用药品的包装应当能防止在运输和储存期间受污染和不可接受的变质。

5.13.4 In blinded trials, the coding system for the investigational product(s) should include a mechanism that permits rapid identification of the product(s) in case of a medical emergency, but does not permit undetectable breaks of the blinding.

在盲法试验中，试验用药品的编码系统应当包括一种在医学紧急情况下允许迅速鉴别药品、但不允许不可监测的破盲机制。

5.13.5 If significant formulation changes are made in the investigational or comparator product(s) during the course of clinical development, the results of any additional studies of the formulated product(s) (e.g. stability, dissolution rate, bioavailability) needed to assess whether these changes would significantly alter the pharmacokinetic profile of the product should be available prior to the use of the new formulation in clinical trials.

在临床研究其间如果试验用药品或对照产品的配方有明显改变，应当在新制剂用于临床试验之前获得制剂产品的附加研究结果（如稳定性、溶出速率，生物利用度），以评价这些改变是否明显改变产品药代动力学特征。

5.14 Supplying and Handling Investigational Product(s)　试验药品的供应和管理

5.14.1 The sponsor is responsible for supplying the investigator(s)/institution(s) with the investigational product(s).

申办者负责向研究者/研究机构提供试验用药品

5.14.2 The sponsor should not supply an investigator/institution with the investigational product(s) until the sponsor obtains all required documentation (e.g. approval/favourable opinion from IRB/IEC and regulatory authority(ies)).

申办者在得到全部多需要文件（如 IRB/IEC 和管理当局的批准/赞成意见）之前不得向研究者/研究机构提供试验药物。

5.14.3 The sponsor should ensure that written procedures include instructions that the investigator/institution should follow for the handling and storage of investigational product(s) for the trial and documentation thereof. The procedures should address adequate and safe receipt, handling, storage, dispensing, retrieval of unused product from subjects, and return of unused investigational product(s) to the sponsor (or alternative disposition if authorized by the sponsor and in compliance with the applicable regulatory requirement(s)).

申办者应当确保书面操作程序包含研究者/研究机构应当遵循的关于试验用药品的处理和储存的说明及其文件。程序应当说明适当和安全的接受、处理、储存、分发、从对象处取回未使用的药物以及将未使用的试验用药品返回给申办者（或经申办者授权并遵照适用管理要求销毁）。

5.14.4 The sponsor should:

申办者应当：

a) Ensure timely delivery of investigational product(s) to the investigator(s).

确保按时将试验用药品送达研究者

b) Maintain records that document shipment, receipt, disposition, return, and destruction of the investigational product(s) (see 8. Essential Documents for the Conduct of a Clinical Trial).

保存证明运输、接收、分发、收回和销毁试验用药品的记录（见 8.实施临床试验的基本文件）

c) Maintain a system for retrieving investigational products and documenting this retrieval (e.g. for deficient product recall, reclaim after trial completion, expired product reclaim).

有一个取回试验用药品和记录取回的规定（如有缺陷产品的收回，在试验结束后归还，过期药品归还）。

d) Maintain a system for the disposition of unused investigational product(s) and for the documentation of this disposition.

有一个处置未使用研究药品和记录这种处置的规定。

5.14.5 The sponsor should: 申办者应当

a) Take steps to ensure that the investigational product(s) are stable over the period of use.

采取步骤以保证试验药品在整个使用期内的稳定性。

b) Maintain sufficient quantities of the investigational product(s) used in the trials to reconfirm specifications, should this become necessary, and maintain records of batch sample analyses and characteristics. To the extent stability permits, samples should be retained either until the analyses of the trial data are complete or as required by the applicable regulatory requirement(s), whichever represents the longer retention period.

维持足够数量的用于试验中的试验用药品，以在万一有必要时再确认其规格，并保存批样分析和特性记录。只要产品稳定性许可，样品应当被保留到试验数据分析完成或适用管理要求的需要时间，取两者中较长的期限。

5.15 Record Access 记录访问

5.15.1 The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) provide direct access to source data/documents for trial-related monitoring, audits, IRB/IEC review, and regulatory inspection.

申办者应当确保在方按中或其他书面协议中已经说明，研究者/研究机构应允许试验有关的监察员、稽查员、IRB/IEC 审评和管理部门视察直接访问原始数据。

5.15.2 The sponsor should verify that each subject has consented, in writing, to direct access to his/her original medical records for trial-related monitoring, audit, IRB/IEC review, and regulatory inspection.

申办者应当核实，每一例对象已经书面同意，在进行鱼试验相关的检查、稽查、IRB/IEC 审评和管理部门视察时直接访问他/她的原始医学记录

5.16 Safety Information 安全性资料

5.16.1 The sponsor is responsible for the ongoing safety evaluation of the investigational product(s).

申办者负责试验用药品正在进行的安全性评价。

5.16.2 The sponsor should promptly notify all concerned investigator(s)/institution(s) and the regulatory authority(ies) of findings that could affect adversely the safety of subjects, impact the conduct of the trial, or alter the IRB/IEC's approval/favourable opinion to continue the trial.

申办者应当立即通知所有有关研究者/研究机构和管理当局关于可能对对象的安全性有不良影响、影响试验实施的或改变 IRB/IEC 对继续试验的批准/赞成的发现。

5.17 Adverse Drug Reaction Reporting 药品不良反应报告

5.17.1 The sponsor should expedite the reporting to all concerned investigator(s)/institutions(s), to the IRB(s)/IEC(s), where required, and to the regulatory authority(ies) of all adverse drug reactions (ADRs) that are both serious and unexpected.

申办者应当迅速向所有有关研究者/研究机构、有关的 IRB/IEC、管理当局报告所有严重的和非预期的药品不良反应。

5.17.2 Such expedited reports should comply with the applicable regulatory requirement(s) and with the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

这种快速报告应当符合适用管理要求和《ＩＣＨ临床安全性数据管理指导原则：快速报告的定义和标准》

5.17.3 The sponsor should submit to the regulatory authority(ies) all safety updates and periodic reports, as required by applicable regulatory requirement(s).

申办者应当根据使用管理要求向管理当局提交全部安全性更新和定期报告。

5.18 Monitoring 监查

5.18.1 Purpose 目的

The purposes of trial monitoring are to verify that:

试验监查的目的是核实

a) The rights and well-being of human subjects are protected.

对象的权利和健康得到保护

b) The reported trial data are accurate, complete, and verifiable from source documents.

所报告的试验数据是准确和完整的，并能从原始文件得到证实。

c) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

试验的实施符合最近批准的方按/方按修改，符合ＧＣＰ和适用管理要求

5.18.2 Selection and Qualifications of Monitors

选择合格的监查员

a) Monitors should be appointed by the sponsor.

监察员应当由申办者指定

b) Monitors should be appropriately trained, and should have the scientific and/or clinical knowledge needed to monitor the trial adequately. A monitor's qualifications should be documented.

监察员应当受过核实的培训，应当有足够的监察试验的科学/活临床知识。监察员的资格应当有文件证明。

c) Monitors should be thoroughly familiar with the investigational product(s), the protocol, written informed consent form and any other written information to be provided to subjects, the sponsor's SOPs, GCP, and the applicable regulatory requirement(s).

监察员应当透彻了解试验用药品、研究方按、知情同意书和其他提供给对象的书面资料、申办者的各种ＳＯＰ、ＧＣＰ和适用管理要求。

5.18.3 Extent and Nature of Monitoring

监查的范围和性质

The sponsor should ensure that the trials are adequately monitored. The sponsor should determine the appropriate extent and nature of monitoring. The determination of the xtent and nature of monitoring should be based on considerations such as the objective, purpose, design, complexity, blinding, size, and endpoints of the trial. In general there is a need for on-site monitoring, before, during, and after the trial; however in exceptional circumstances the sponsor may determine that central monitoring in conjunction with procedures such as investigators' training and meetings, and extensive written guidance can assure appropriate conduct of the trial in accordance with GCP. Statistically controlled sampling may be an acceptable method for selecting the data to be verified.

申办者应当保证试验得到适当的监察。申办者应当决定监察的合适范围和性质。监察的范围和性质应当根据目标、目的、设计、复杂性、盲法、样本大小和试验终点确定。通常需要在试验前、试验期间和试验后进行现场监察，但是在特别的场合，申办者可以决定与某些步骤，如研究人员培训和研究人员会议，合在一起的终点监察。多方面的书面指导原则可以保证恰当地按照ＧＣＰ实施试验。统计学上控制地抽样可能是一个可以接受地选择需要核对的数据的方法。

5.18.4 Monitor's Responsibilities

监查员的责任

The monitor(s) in accordance with the sponsor’s requirements should ensure that the trial is conducted and documented properly by carrying out the following activities when relevant and necessary to the trial and the trial site:

按照申办者的要求，在对试验和试验单位恰当和必要时，监察员应当通过下列活动保证试验被正确的实施和记录：

a) Acting as the main line of communication between the sponsor and the investigator.

在申办者和研究者之间的交流起干线作用。

b) Verifying that the investigator has adequate qualifications and resources (see 4.1, 4.2, 5.6) and remain adequate throughout the trial period, that facilities, including laboratories, equipment, and staff, are adequate to safely and properly conduct the trial and remain adequate throughout the trial period.

验证研究者有足够的资格和自愿（见 4.1，4.2，5.6），并且在整个试验期间仍然是足够的；设备，包括实验室、仪器和职员足以安全和正确地实施试验，并在整个试验期间也是足够地。

c) Verifying, for the investigational product(s):

对于试验用药品，核实：

i) That storage times and conditions are acceptable, and that supplies are sufficient throughout the trial.

储存时间和条件是可以接受的，在整个试验中供应充足

ii) That the investigational product(s) are supplied only to subjects who are eligible to receive it and at the protocol specified dose(s).

试验用药品只按试验方案规定地剂量提供给合格地对象

iii) That subjects are provided with necessary instruction on properly using, handling, storing, and returning the investigational product(s).

向对象提供正确使用、处理、储存和归还试验用药品地说明

iv) That the receipt, use, and return of the investigational product(s) at the trial sites are controlled and documented adequately.

在试验单位，试验用药品接收、使用和归还试验用药品地说明

v) That the disposition of unused investigational product(s) at the trial sites complies with applicable regulatory requirement(s) and is in accordance with the sponsor.

试验单位对未使用地试验用药品地处置符合管理要求和申办者地要求。

d) Verifying that the investigator follows the approved protocol and all approved amendment(s), if any.

核实研究者遵循已批准地方案和所有已批准的修改

e) Verifying that written informed consent was obtained before each subject's participation in the trial.

核实在每个研究对象参加试验前已经得到书面的知情同意

f) Ensuring that the investigator receives the current Investigator's Brochure, all documents, and all trial supplies needed to conduct the trial properly and to comply with the applicable regulatory requirement(s).

确保研究者收到最近的研究者手册、所有的文件和按照适用管理要求正确实施试验必需的所有试验用品。

g) Ensuring that the investigator and the investigator's trial staff are adequately informed about the trial.

保证研究者及其试验职员对试验有充分的知识

h) Verifying that the investigator and the investigator's trial staff are performing the specified trial functions, in accordance with the protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals.

核实研究者及其试验职员正在按照方案和申办者与研究者/研究机构之间的其他书面协议执行特定的试验职责，没有将这些职责委派给未经授权的人。

i) Verifying that the investigator is enrolling only eligible subjects.

核实研究者只招募合格的对象

j) Reporting the subject recruitment rate.

报告对象招募速度

k) Verifying that source documents and other trial records are accurate, complete, kept up-to-date and maintained.

核实源文件和其他试验记录是准确的、完整的、保持更新并都保存着

l) Verifying that the investigator provides all the required reports, notifications, applications, and submissions, and that these documents are accurate, complete, timely, legible, dated, and identify the trial.

确保研究者提供所有需要的报告、通知、申请和递交的文件，并且这些文件都是准确、完整、按时、清晰易读、注明日期和试验鉴别

m) Checking the accuracy and completeness of the CRF entries, source documents and other trial-related records against each other. The monitor specifically should verify that:

彼此对照检查ＣＲＦ记录、源文件和其他试验有感记录的准确系国内和完整性。监察员尤其应当检查：

i) The data required by the protocol are reported accurately on the CRFs and are consistent with the

source documents.

试验方案需要的数据在ＣＲＦ上有准确记录，并与源文件一致

ii) Any dose and/or therapy modifications are well documented for each of the trial subjects.

每一位试验对象的剂量和治疗的任何修改均与有良好记录

iii) Adverse events, concomitant medications and intercurrent illnesses are reported in accordance with the protocol on the CRFs.

不良事件，伴随用药和试验过程中发生的疾病根据方案在 CRF 上作了报告

iv) Visits that the subjects fail to make, tests that are not conducted, and examinations that are not performed are clearly reported as such on the CRFs.

试验未来随访，未进行的检验，未完成的检查应同样在 CRF 上有清楚报告

v) All withdrawals and dropouts of enrolled subjects from the trial are reported and explained on the CRFs.

已接纳对象的撤出或中途退出试验应在 CRF 上报告并给出说明

n) Informing the investigator of any CRF entry error, omission, or illegibility. The monitor should ensure that appropriate corrections, additions, or deletions are made, dated, explained (if necessary), and initialled by the investigator or by a member of the investigator's trial staff who is authorized to initial CRF changes for the investigator. This authorization should be documented.

通知研究者关于 CRF 的填写错误、遗漏或字迹不清楚。监察员应当确保所做的更正、附加或删除是合宜的、注明日期的、有说明的（如有必要），并由研究者或研究者授权修正的ＣＲＦ的试验工作人员签上姓名首字母。授权应当有证明。

o) Determining whether all adverse events (AEs) are appropriately reported within the time periods required by GCP, the protocol, the IRB/IEC, the sponsor, and the applicable regulatory requirement(s).

确定是否所有不良事件(AE)在 GCP、试验方案、IRB/IEC、申办者和适用管理要求所规定的期限内恰当地作了报告。

p) Determining whether the investigator is maintaining the essential documents (see 8. Essential Documents for the Conduct of a Clinical Trial).

确定研究者是否保持有基本文件(见 8.实施临床试验地基本文件)

q) Communicating deviations from the protocol, SOPs, GCP, and the applicable regulatory requirements to the investigator and taking appropriate action designed to prevent recurrence of the detected deviations.

通知研究者关于与试验方案、SOP、GCP 和适用管理要求地偏离，并采取适当措施防止再发生上述偏离。

5.18.5 Monitoring Procedures

监查程序

The monitor(s) should follow the sponsor's established written SOPs as well as those procedures that are specified by the sponsor for monitoring a specific trial.

监察者应当遵循申办者制订地各种 SOP 以及申办者为监察一个特定试验制订地特定程序。

5.18.6 Monitoring Report

监查报告

a) The monitor should submit a written report to the sponsor after each trial-site visit or trial-related communication.

监察者在每一次进行试验单位现场访问或与试验有关地交流后，应当向申办者递交书面报告。

b) Reports should include the date, site, name of the monitor, and name of the investigator or other individual(s) contacted.

报告应当包括日期、地点、监察者姓名、研究者或接触地其他人员的姓名

c) Reports should include a summary of what the monitor reviewed and the monitor's statements concerning the significant findings/facts, deviations and deficiencies, conclusions, actions taken or to be taken and/or actions recommended to secure compliance.

报告应当包括监察者检查内容的摘要，监察员关于有意义发现/事实的陈述，偏离和不足，结论，已采取的或将采取的措施，和/或为保护依从性建议的措施。

d) The review and follow-up of the monitoring report with the sponsor should be documented by the sponsor's designated representative.

申办者对监察报告的审评和随访应当有申办者制订的代表作成文件

5.19 Audit 稽查

If or when sponsors perform audits, as part of implementing quality assurance, they should consider:

作为实现质量保证的一部分，申办者进行稽查时应当考虑

5.19.1 Purpose

目的

The purpose of a sponsor's audit, which is independent of and separate from routine monitoring or quality control functions, should be to evaluate trial conduct and compliance with the protocol, SOPs, GCP, and the applicable regulatory requirements.

独立的、与常规监察或质量控制分开的申办者的稽查，其目的应当是评价试验的实施和对试验方案、SOP、GCP 和适用管理要求的依从性

5.19.2 Selection and Qualification of Auditors

稽查员的选择和资格

a) The sponsor should appoint individuals, who are independent of the clinical trials/systems, to conduct

audits.

申办者应当指定一个独立于临床试验/体系的人实施稽查

b) The sponsor should ensure that the auditors are qualified by training and experience to conduct audits properly. An auditor's qualifications should be documented.

申办者应当保证稽查员是通过培训合格并有经验正确的实施稽查。稽查员的资格应当有证明。

5.19.3 Auditing Procedures

稽查程序

The sponsor should ensure that the auditing of clinical trials/systems is conducted in accordance with the sponsor's written procedures on what to audit, how to audit, the frequency of audits, and the form and content of audit reports.

申办者应当保证临床试验/体系是按照申办者的关于稽查什么、如何稽查、稽查频度的书面程序、稽查报告表及其内容进行

a) The sponsor's audit plan and procedures for a trial audit should be guided by the importance of the trial to submissions to regulatory authorities, the number of subjects in the trial, the type and complexity of the trial, the level of risks to the trial subjects, and any identified problem(s).

申办者方对一个试验稽查的稽查计划和程序应当根据试验对于向管理当局提交的重要性、试验中的对象数目、试验的类型和复杂成都、试验对象的风险水平以及所识别的其他问题而定。

b) The observations and findings of the auditor(s) should be documented.

稽查的观察资料和发现应当做成文件

c) To preserve the independence and value of the audit function, the regulatory authority(ies) should not routinely request the audit reports. Regulatory authority(ies) may seek access to an audit report on a case by case basis when evidence of serious GCP non-compliance exists, or in the course of legal proceedings.

未保持稽查职能的独立性和价值，管理当局不应当例行公事地要求稽查报告。当有严重不依从 GCP 地证据存在时，或在法律诉讼期间，管理当局可能寻求逐例试验稽查报告。

d) When required by applicable law or regulation, the sponsor should provide an audit certificate.

在适用法律或法规要求，申办者应当提供稽查许可证。

5.20 Noncompliance 不依从性

5.20.1 Noncompliance with the protocol, SOPs, GCP, and/or applicable regulatory requirement(s) by an investigator/institution, or by member(s) of the sponsor's staff should lead to prompt action by the sponsor to secure compliance.

一个研究者/研究机构或申办者的职员对于试验方案、SOP、GCP 和/或适用管理要求不依从时，申办者应当立即采取措施促成依从性。

5.20.2 If the monitoring and/or auditing identifies serious and/or persistent noncompliance on the part of an investigator/institution, the sponsor should terminate the investigator's/institution's participation in the trial. When an investigator's/institution's participation is terminated because of noncompliance, the sponsor should notify promptly the regulatory authority(ies).

如果监察和/研究机构的某一部门严重的和/或持续的不依从，申办者应当停止研究者/研究机构参加临床试验。一个研究者/研究机构因为不依从被终止参加试验时，申办者应当立即通报管理当局。

5.21 Premature Termination or Suspension of a Trial

一个试验的过早终止或暂停

If a trial is prematurely terminated or suspended, the sponsor should promptly inform the investigators/ institutions, and the regulatory authority(ies) of the termination or suspension and the reason(s) for the termination or suspension. The IRB/IEC should also be informed promptly and provided the reason(s) for the termination or suspension by the sponsor or by the investigator/institution, as specified by the applicable regulatory requirement(s).

如果一个试验过早终止或停止，申办者应当立即通知各研究者/研究机构以及管理当局关于终止或暂停事宜及其理由。根据适用管理要求的说明，申办者或研究者/研究机构还应当立即通知 IRB/IEC 并提供终止或暂停的理由。

5.22 Clinical Trial/Study Reports 临床试验/研究报告

Whether the trial is completed or prematurely terminated, the sponsor should ensure that the clinical trial reports are prepared and provided to the regulatory agency(ies) as required by the applicable regulatory requirement(s). The sponsor should also ensure that the clinical trial reports in marketing applications meet the standards of the ICH Guideline for Structure and Content of Clinical Study Reports. (NOTE: The ICH Guideline for Structure and Content of Clinical Study Reports specifies that abbreviated study reports may be acceptable in certain cases.)

不管临床试验是完成了还是过早停止，申办者应当确保按照适用管理规定要求准备临床试验报告，并提供给管理部门。申办者也应当保证，上市申请的临床试验报告符合《ICH 临床研究报告的结构和内容指导原则》的标准。（注：《ICH 临床研究报告的结构和内容指导原则》说明了在某些情况下 间断的研究报告是可接受的。

5.23 Multicentre Trials 多中心试验

For multicentre trials, the sponsor should ensure that:

对于多中心试验，申办者应当保证：

5.23.1 All investigators conduct the trial in strict compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies), and given approval/favourable opinion by the IRB/IEC.

实施试验的所有研究者严格遵循申办者同意的、必要时经管理当局同意并得到 IRB/IEC 批准/赞成意见的试验方案。

5.23.2 The CRFs are designed to capture the required data at all multicentre trial sites. For those investigators who are collecting additional data, supplemental CRFs should also be provided that are designed to capture the additional data.

在多中心研究中，CRF 被设计用来记录所需要的数据。对于那些收集附加数据的研究者，应向他们提供设计来用于收集额外数据的补充 CRF

5.23.3 The responsibilities of coordinating investigator(s) and the other participating investigators are documented prior to the start of the trial.

协调研究者和其他主要研究者的职责要在试验开始前确认

5.23.4 All investigators are given instructions on following the protocol, on complying with a uniform set of standards for the assessment of clinical and laboratory findings, and on completing the CRFs.

向所有研究者提供关于理解试验方案、遵循评价临床和实验室发现的同意标准以及完成 CRF 的指导性原则

5.23.5 Communication between investigators is facilitated.

促进研究者之间的交流

6. CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT(S)

临床试验方案和方案增补

The contents of a trial protocol should generally include the following topics. However, site specific information may be provided on separate protocol page(s), or addressed in a separate agreement, and some of the information listed below may be contained in other protocol referenced documents, such as an Investigator's Brochure.

试验方案的内容通常应当包括以下主题。但是试验单位的特别信息可以分开列在方案的单独一（几）页上，或写在一个单独的协议中，下列的某些资料可写在方案的其他参考文件，如研究者手册中。

6.1 General Information 一般资料

6.1.1 Protocol title, protocol identifying number, and date. Any amendment(s) should also bear the amendment number(s) and date(s).

试验方案的题目，方案鉴别号和日期。任何修改应当有修改编号和日期

6.1.2 Name and address of the sponsor and monitor (if other than the sponsor).

申办者和监察员（如与申办者非同一个人）的姓名和地点

6.1.3 Name and title of the person(s) authorized to sign the protocol and the protocol amendment(s) for the sponsor.

被授权为研究者签署试验方案和方案修改人员的姓名和头衔

6.1.4 Name, title, address, and telephone number(s) of the sponsor's medical expert (or dentist when

appropriate) for the trial.

申办者方的医学专家（或牙医，如合适）的姓名、头衔、地址和电话号码

6.1.5 Name and title of the investigator(s) who is (are) responsible for conducting the trial, and the address and telephone number(s) of the trial site(s).

负责实施试验的研究者和研究者的姓名和头衔，以及试验单位的电话号码

6.1.6 Name, title, address, and telephone number(s) of the qualified physician (or dentist, if applicable), who is responsible for all trial-site related medical (or dental) decisions (if other than investigator).

负责试验单位所有医学（或牙医）决定的有资格医生（或牙医）（如与研究者不是同一人）的姓名、头衔、地址及电话号码

6.1.7 Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the trial.

临床试验室和其他医学和/或技术部门、和/或参与试验的机构的名称和地址

6.2 Background Information 背景资料

6.2.1 Name and description of the investigational product(s).

试验用药品的名称和描述

6.2.2 A summary of findings from nonclinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial.

非临床研究中有潜在临床意义的发现，临床试验中与试验有关的发现摘要

6.2.3 Summary of the known and potential risks and benefits, if any, to human subjects.

对人类（如有）已知的和潜在的风险和利益的摘要

6.2.4 Description of and justification for the route of administration, dosage, dosage regimen, and treatment period(s).

所用的给药途径、剂量、剂量方案和治疗时间的描述和理由

6.2.5 A statement that the trial will be conducted in compliance with the protocol, GCP and the applicable regulatory requirement(s).

将会按照方案、GCP 和适用管理要求进行试验的陈述

6.2.6 Description of the population to be studied.

试验人群描述

6.2.7 References to literature and data that are relevant to the trial, and that provide background for the trial.

与试验相关，并提供试验背景资料的文献和数据

6.3 Trial Objectives and Purpose 试验目标和目的

A detailed description of the objectives and the purpose of the trial.

详细描述试验的目标和目的

6.4 Trial Design 试验设计

The scientific integrity of the trial and the credibility of the data from the trial depend substantially on the trial design. A description of the trial design, should include:

试验的科学完整性和试验数据的可信性主要取决于试验设计。试验设计的描述应当包括：

6.4.1 A specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the trial.

试验期间要测量的主要终点和次要终点（如有）的详细说明

6.4.2 A description of the type/design of trial to be conducted (e.g. double-blind, placebo-controlled, parallel design) and a schematic diagram of trial design, procedures and stages.

试验期间要测量的主要终点和次要终点（如有）的详细说明

6.4.3 A description of the measures taken to minimize/avoid bias, including:

减少/避免偏倚所采取的措施的描述，包括：

a) Randomization. 随机

b) Blinding. 盲法

6.4.4 A description of the trial treatment(s) and the dosage and dosage regimen of the investigational product(s). Also include a description of the dosage form, packaging, and labelling of the investigational product(s).

试验治疗和试验用药品的剂量、剂量方案的描述，包括试验用药品的剂型、包装、标签的描述

6.4.5 The expected duration of subject participation, and a description of the sequence and duration of all trial periods, including follow-up, if any.

对象参加试验的预期持续时间；全部试验周期，包括随访的次序和期限的说明

6.4.6 A description of the "stopping rules" or "discontinuation criteria" for individual subjects, parts of trial and entire trial.

关于停止个别对象、部分试验和全部试验的“停止规则”或“终止标准”的描述

6.4.7 Accountability procedures for the investigational product(s), including the placebo(s) and comparator(s), if any.

试验用药品，也包括安慰剂和对照药物的可计数性

6.4.8 Maintenance of trial treatment randomization codes and procedures for breaking codes.

保持试验治疗随机化编码和破盲程序

6.4.9 The identification of any data to be recorded directly on the CRFs (i.e. no prior written or electronic record of data), and to be considered to be source data.

直接记录在 CRF 上的所有数据（即不是先前写下的数据或电子记录数据）和被考虑作为源数据的鉴别

6.5 Selection and Withdrawal of Subjects 受试者的选择和退出

6.5.1 Subject inclusion criteria. 受试者入选标准

6.5.2 Subject exclusion criteria. 受试者排除标准

6.5.3 Subject withdrawal criteria (i.e. terminating investigational product treatment/trial treatment) and procedures specifying:

对象的停止标准（即停止试验用药品治疗/试验治疗）和程序说明：

a) When and how to withdraw subjects from the trial/ investigational product treatment.

什么时候和怎样停止对象的试验/试验用药品治疗

b) The type and timing of the data to be collected for withdrawn subjects.

从退出对象收集的数据的类型和时间选择

c) Whether and how subjects are to be replaced.

是否和如何替换对象

d) The follow-up for subjects withdrawn from investigational product treatment/trial treatment.

退出试验用药品治疗/试验治疗的对象的随访

6.6 Treatment of Subjects 受试者的治疗

6.6.1 The treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the route/mode(s) of administration, and the treatment period(s), including the follow-up period(s) for subjects for each investigational product treatment/trial treatment group/arm of the trial.

所给予的治疗，包括所有试验用药品的名称、剂量、给药方案、给药的途径/方法和疗程，包括对象在每个试验用药品治疗/试验治疗组/试验待命中断的随访期。

6.6.2 Medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial.

在试验前和/或试验期间允许的（包括营救性治疗）和不允许药物治疗/治疗

6.6.3 Procedures for monitoring subject compliance.

监察对象依从性的程序

6.7 Assessment of Efficacy 有效性评估

6.7.1 Specification of the efficacy parameters.

有效性指标的认定

6.7.2 Methods and timing for assessing, recording, and analysing of efficacy parameters.

评价，记录和分析有效性参数的方法和时间选择

6.8 Assessment of Safety 安全性评估

6.8.1 Specification of safety parameters.

安全性指标的认定

6.8.2 The methods and timing for assessing, recording, and analysing safety parameters.

评价、记录和分析安全性参数的方法和时间选择

6.8.3 Procedures for eliciting reports of and for recording and reporting adverse event and intercurrent illnesses.

记录和报告不良事件与并发疾病的程序，和发出报告的程序

6.8.4 The type and duration of the follow-up of subjects after adverse events.

经历不良事件后对象的随访形式和期限

6.9 Statistics 统计

6.9.1 A description of the statistical methods to be employed, including timing of any planned interim analysis(ses).

描述将采用的统计方法，包括计划进行中期分析的时间选择

6.9.2 The number of subjects planned to be enrolled. In multicentre trials, the numbers of enrolled subjects projected for each trial site should be specified. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.

计划招募的对象数目。如为多中心试验，应当说明每个试验点计划招募的对象熟。样本大小的选择理由，包括试验的把握度和临床方面的理由

6.9.3 The level of significance to be used.

所采用的显著性水平

6.9.4 Criteria for the termination of the trial.

终止试验的标准

6.9.5 Procedure for accounting for missing, unused, and spurious data.

处理缺失数据、未用数据和不合理数据的程序

6.9.6 Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in protocol and/or in the final report, as appropriate).

报告偏离原定统计计划的程序（原定统计计划的任何变更应当在方案中和/或在最终报告中说明并给出理由）

6.9.7 The selection of subjects to be included in the analyses (e.g. all randomized subjects, all dosed subjects, all eligible subjects, evaluable subjects).

列入分析对象的选择（如所有随机化的对象，所有给药的对象，所有合格的对象，可评价的对象）

6.10 Direct Access to Source Data/Documents 直接查阅原始数据或文件

The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s), providing direct access to source data/documents.

申办者应当确保在方案中或在其他书面协议中说明了研究者/研究机构应当允许试验有关的监察、稽查、IRB/IEC 审评和管理部门视察，直接访问源数据/文件

6.11 Quality Control and Quality Assurance 质量控制和质量保证

6.12 Ethics 伦理

Description of ethical considerations relating to the trial.

描述与试验有关的伦理学考虑

6.13 Data Handling and Record Keeping 数据处理和记录保存

6.14 Financing and Insurance 财务与保险

Financing and insurance if not addressed in a separate agreement.

未在另外协议书中提到的财务与保险

6.15 Publication Policy 出版策略

Publication policy, if not addressed in a separate agreement.

未在另外协议书中提到的出版策略

6.16 Supplements 补充

(NOTE: Since the protocol and the clinical trial/study report are closely related, further relevant information can be found in the ICH Guideline for Structure and Content of Clinical Study Reports.)

（注：由于试验方案与临床试验/研究报告密切相关，在《ICH 临床研究报告的结构和内容指导原则》中可找到更多的相关资料。）

7. INVESTIGATOR'S BROCHURE 研究者手册

7.1 Introduction 引言

The Investigator's Brochure (IB) is a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects. Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such as the dose, dose frequency/interval, methods of administration: and safety monitoring procedures. The IB also provides insight to support the clinical management of the study subjects during the course of the clinical trial. The information should be presented in a concise, simple, objective, balanced, and non-promotional form that enables a clinician, or potential investigator, to understand it and make his/her own unbiased risk-benefit assessment of the appropriateness of the proposed trial. For this reason, a medically qualified person should generally participate in the editing of an IB, but the contents of the IB should be approved by the disciplines that generated the described data.

研究者手册（IB）是与试验用药品的人类对象研究有关的临床资料和非临床资料的汇编。手册的目的是向研究者和参与试验的其他人员提供资料，帮助他们了解方案的许多关键特征的基本原理并遵循这些关键特征，如剂量，剂量频度/间隔，给药方法和安全性监察程序。IB 也提供支持在临床试验期间对研究对象的临床管理的见解。资料应当是简明、简单、可观、均衡、非宣传性的形式，使医生或潜在的研究者了解手册的内容，对于所提议的试验的合理性作出他们自己的无偏倚的风险－利益评价。因此，合格的医学人士一般会参加 IB 的编写，但是 IB 的内同应当得到产生所描述地数据的学科的认可。

This guideline delineates the minimum information that should be included in an IB and provides suggestions for its layout. It is expected that the type and extent of information available will vary with the stage of development of the investigational product. If the investigational product is marketed and its pharmacology is widely understood by medical practitioners, an extensive IB may not be necessary. Where permitted by regulatory authorities, a basic product information brochure, package leaflet, or labelling may be an appropriate alternative, provided that it includes current, comprehensive, and detailed information on all aspects of the investigational product that might be of importance to the investigator. If a marketed product is being studied for a new use (i.e., a new indication), an IB specific to that new use should be prepared. The IB should be reviewed at least annually and revised as necessary in compliance with a sponsor's written

procedures. More frequent revision may be appropriate depending on the stage of development and the generation of relevant new information. However, in accordance with Good Clinical Practice, relevant new information may be so important that it should be communicated to the investigators, and possibly to the Institutional Review Boards (IRBs)/Independent Ethics Committees (IECs) and/or regulatory authorities before it is included in a revised IB.

本指导原则描述的是 IB 应当包括最低限度资料并为其编排提出建议。可以预料，可用到的资料类型和范围将随试验用药品的开发阶段变化。如果试验用药品上市，并且它的药理学为广大医学从业者了解，可能就不需要一本详尽的 IB。若管理当局许可，一本基本的产品资料手册，包装说明，或标签可能是合适的选择，只要他们包括对研究者是重要的关于试验用药品最近的、综合性的、详细的各方面的资料。如果正在研究一个已上市产品的新用途（即一个新的适应证），应当特别准备一份关于该新用途的 IB.IB 至少应当一年审评一次，必要时按照申办者的书面程序修改。根据新药的发展阶段和得到的有关新资料，或许需要更频繁地进行修改。但是，依照 GCP 要求，有关地新资料可能很重要，在将其列入修改地 IB 之前，需要通知研究者、机构审评委员会（IRB）/独立的伦理委员会（IEC），和/或管理当局。

Generally, the sponsor is responsible for ensuring that an up-to-date IB is made available to the investigator(s) and the investigators are responsible for providing the up-to-date IB to the responsible IRBs/IECs. In the case of an investigator sponsored trial, the sponsor-investigator should determine whether a brochure is available from the commercial manufacturer. If the investigational product is provided by the sponsor-investigator, then he or she should provide the necessary information to the trial personnel. In cases where preparation of a formal IB is impractical, the sponsor-investigator should provide, as a substitute, an expanded background information section in the trial protocol that contains the minimum current information described in this guideline.

通常，申办者负责保证向研究者提供最新的 IB，研究者有责任将最新的 IB 提供给负责的 IRB/IEC。在由研究者申办试验时，申办者－研究者应当决定手册是否可从制造商处得到。如果由申办者－研究者提供试验用药品，那么他或她应当向言菊人员提供必要的资料。当准备一个正式的 IB 是不符合实际时，作为一种替代，申办者－研究者应当在试验方案中提供扩展的背景资料，包含本指导原则所述的最低限度的最近资料。

7.2 General Considerations 概述

The IB should include: 研究者手册应包括以下内容

7.2.1 Title Page

标题页

This should provide the sponsor's name, the identity of each investigational product (i.e., research number, chemical or approved generic name, and trade name(s) where legally permissible and desired by the sponsor), and the release date. It is also suggested that an edition number, and a reference to the number and date of the edition it supersedes, be provided. An example is given in Appendix 1.

扉页应当提供申办者姓名，每一个试验用药品的鉴别（即研究编号，化学命或已批准的通用名，法律允许的申办者所希望的商品名），以及发布日期。还建议列出版本号码以及该号码的参考索引，以及该版本替换和被批准的日期。示例见附录 1

7.2.2 Confidentiality Statement

保密声明

The sponsor may wish to include a statement instructing the investigator/recipients to treat the IB as a confidential document for the sole information and use of the investigator's team and the IRB/IEC.

申办者可能希望包括一段陈述，指示研究者/收件人将 IB 做机密文件处理，仅供研究人员小组和 IRB/IEC 使用。

7.3 Contents of the Investigator's Brochure IB 内容

The IB should contain the following sections, each with literature references where appropriate:

IB 应当包括下列章节，每一节附参考文献：

7.3.1 Table of Contents

目录

An example of the Table of Contents is given in Appendix 2

附录 2 为目录的例子

7.3.2 Summary

摘要

A brief summary (preferably not exceeding two pages) should be given, highlighting the significant physical, chemical, pharmaceutical, pharmacological, toxicological, pharmacokinetic, metabolic, and clinical information available that is relevant to the stage of clinical development of the investigational product.

应当有一个简短的摘要（最好不超过 2 页），重点是与试验用药品发展阶段有关的、有意义的物理、化学、药学、药理学、毒理学、药代动力学、代谢学和临床资料

7.3.3 Introduction

前言

A brief introductory statement should be provided that contains the chemical name (and generic and trade name(s) when approved) of the investigational product(s), all active ingredients, the investigational product (s) pharmacological class and its expected position within this class (e.g. advantages), the rationale for performing research with the investigational product(s), and the anticipated prophylactic, therapeutic, or diagnostic indication(s). Finally, the introductory statement should provide the general approach to be followed in evaluating the investigational product.

应当有一个简短的前言，说明试验用药品的化学名（批准时的通用名和商品名），所有活性成分，试验用药品的药理学分类和它在这一类中的预期位置（如优势），试验用药品正在进行研究的基本原理，预期的预防、治疗或诊断适应证。最后，前言应当提供评价试验用药品的一般方法。

7.3.4 Physical, Chemical, and Pharmaceutical Properties and Formulation

物理学、化学和药学特性和处方

A description should be provided of the investigational product substance(s) (including the chemical and/or structural formula(e)), and a brief summary should be given of the relevant physical, chemical, and pharmaceutical properties.

应当有关于试验用药品的描述（包括化学式和/或结构式），以及关于物理学、化学和药学特性的简短摘要。

To permit appropriate safety measures to be taken in the course of the trial, a description of the formulation(s) to be used, including excipients, should be provided and justified if clinically relevant. Instructions for the storage and handling of the dosage form(s) should also be given.

在试验过程中允许采取合宜的安全措施，如果临床上相关，应当提供所用配方包括赋形剂的描述，并应提出配方理由。也应当给出制剂储存和处理的说明。

Any structural similarities to other known compounds should be mentioned.

应当提及与其他已知化合物的结构相似性。

7.3.5 Nonclinical Studies

非临床研究

Introduction:

前言

The results of all relevant nonclinical pharmacology, toxicology, pharmacokinetic, and investigational product metabolism studies should be provided in summary form. This summary should address the methodology used, the results, and a discussion of the relevance of the findings to the investigated therapeutic and the possible unfavourable and unintended effects in humans.

应当以摘要形式提供所有非临床的药理学、毒理学、药代动力学和试验用药品的代谢研究的有关结果。摘要应当说明所采用的方法学、结果，以及这些发现对所研究的治疗的关系，和对人类可能的不利与以外的影响。

The information provided may include the following, as appropriate, if known/available: .

如果知道/可以得到，可以适当提供下列资料：

- Species tested
- 试验动物种属
- Number and sex of animals in each group
- 每组动物的数目和性别
- Unit dose (e.g., milligram/kilogram (mg/kg))
- 剂量单位(如 mg 或 kg)
- Dose interval

- 给药间隔
- Route of administration
- 给药途径
- Duration of dosing
- 给药持续时间
- Information on systemic distribution
- 体内分布资料
- Duration of post-exposure follow-up
- 给药后观察期限
- Results, including the following aspects:
- 结果，包括以下方面：
  - Nature and frequency of pharmacological or toxic effects
  - 药理及毒理作用的性质及发生率
  - Severity or intensity of pharmacological or toxic effects
  - 药理及毒理作用的严重程度及强度
  - Time to onset of effects
  - 起效时间
  - Reversibility of effects
  - 作用的可逆性
  - Duration of effects
  - 作用的持续时间
  - Dose response
  - 量效反应

Tabular format/listings should be used whenever possible to enhance the clarity of the presentation.

只要可能应采用表格/列表增强陈述的清晰度

The following sections should discuss the most important findings from the studies, including the dose response of observed effects, the relevance to humans, and any aspects to be studied in humans. If applicable, the effective and nontoxic dose findings in the same animal species should be compared (i.e., the therapeutic index should be discussed).

随后的章节应当讨论研究的最重要发现，包括所观察到的作用的剂量反应关系，与人类的相关性，以及在人类中研究的各个方面。如果合适，在同一动物种属的有效剂量和非毒性剂量的发现应当做

比较（即应当讨论治疗指数）。

The relevance of this information to the proposed human dosing should be addressed. Whenever possible, comparisons should be made in terms of blood/tissue levels rather than on a mg/kg basis.

应当说明这一资料与所提议的人用剂量的相关性。只要可能，应根据血/组织水平而非 mg/kg 进行比较

a) Nonclinical Pharmacology

非临床药理学

A summary of the pharmacological aspects of the investigational product and, where appropriate, its significant metabolites studied in animals, should be included. Such a summary should incorporate studies that assess potential therapeutic activity (e.g. efficacy models, receptor binding, and specificity) as well as those that assess safety (e.g., special studies to assess pharmacological actions other than the intended therapeutic effect(s)).

应当包括试验用药品的药理学方面的摘要，如有可能还包括药品在动物的重要代谢研究摘要。这样一个摘要应当合并评价潜在治疗活性（如有效性模型，受体结合和特异性）以及评价安全性的研究（如不同于评价治疗作用的评价药理学作用的专门研究）

b) Pharmacokinetics and Product Metabolism in Animals

动物中的药物药代动力学及产品的代谢

A summary of the pharmacokinetics and biological transformation and disposition of the investigational product in all species studied should be given. The discussion of the findings should address the absorption and the local and systemic bioavailability of the investigational product and its metabolites, and their relationship to the pharmacological and toxicological findings in animal species.

应当给出试验用药品在所研究种属动物中的药物动力学、生物转化以及处置的摘要。对发现物的讨论应当说明试验用药品的说明及其部位、系统的生物利用度及其代谢，以及它们与人类的药理学和毒理学发现物的关系

c) Toxicology

毒理学

A summary of the toxicological effects found in relevant studies conducted in different animal species should be described under the following headings where appropriate:

在不同动物种属中进行的相关研究所发现的毒理学作用摘要应按以下栏目描述

- Single dose
- 单剂给药
- Repeated dose
- 重复给药
- Carcinogenicity

- 致癌性
- Special studies (e.g. irritancy and sensitisation)
- 特殊研究（如刺激性和致敏性）
- Reproductive toxicity
- 生殖毒性
- Genotoxicity (mutagenicity)
- 遗传毒性

7.3.6 Effects in Humans

人体作用

Introduction:

引言

A thorough discussion of the known effects of the investigational product(s) in humans should be provided, including information on pharmacokinetics, metabolism, pharmacodynamics, dose response, safety, efficacy, and other pharmacological activities. Where possible, a summary of each completed clinical trial should be provided. Information should also be provided regarding results of any use of the investigational product(s) other than from in clinical trials, such as from experience during marketing.

应当提供试验用药品在人类的已知作用的充分讨论，包括关于药物动力学、代谢、药效学、剂量反应、安全性、有效性和其他药理学领域。只要可能，应当提供每一个已经完成的临床试验的摘要。还应当提供试验用药品在临床试验以外的用途的结果，如上市期间的经验。

a) Pharmacokinetics and Product Metabolism in Humans

人体的药物动力学和代谢

A summary of information on the pharmacokinetics of the investigational product(s) should be presented, including the following, if available:

应当写出试验用药品的药物动力学资料摘要，包括以下方面：

- Pharmacokinetics (including metabolism, as appropriate, and absorption, plasma protein binding, distribution, and elimination).

  药物动力学（包括代谢和吸收，血浆蛋白结合，分布和消除）

- Bioavailability of the investigational product (absolute, where possible, and/or relative) using a reference dosage form.

  试验用药品的一个参考剂型的生物利用度（绝对和/或相对生物利用度）

- Population subgroups (e.g., gender, age, and impaired organ function).

  人群亚组（如性别、年龄和脏器功能受损）

- Interactions (e.g., product-product interactions and effects of food).

相互作用（如药物－药物相互作用和药物与食物的相互作用）

- Other pharmacokinetic data (e.g., results of population studies performed within clinical trial(s).

其他药物动力学数据（如在临床试验期间完成的群体研究结果）

b) Safety and Efficacy

安全性和有效性

A summary of information should be provided about the investigational product's/products' (including metabolites, where appropriate) safety, pharmacodynamics, efficacy, and dose response that were obtained from preceding trials in humans (healthy volunteers and/or patients). The implications of this information should be discussed. In cases where a number of clinical trials have been completed, the use of summaries of safety and efficacy across multiple trials by indications in subgroups may provide a clear presentation of the data. Tabular summaries of adverse drug reactions for all the clinical trials (including those for all the studied indications) would be useful. Important differences in adverse drug reaction patterns/incidences across indications or subgroups should be discussed.

应当提供从先前人体试验（健康志愿者和/或病人）中得到的关于试验用药品（包括代谢物）的安全性、药效学、有效性和剂量反应资料的摘要。应讨论这些资料的含义。如果已经完成许多临床试验，从多个研究以及亚组适应证的安全性和有效性得出的摘要可能清楚地展示有关数据。将所有临床试验地药品不良反应制成表格的摘要（包括所有被研究的适应证）将是有用的。对于在适应证或亚组之间药品不良反应类型/发生率的重要差异应当进行讨论

The IB should provide a description of the possible risks and adverse drug reactions to be anticipated on the basis of prior experiences with the product under investigation and with related products. A description should also be provided of the precautions or special monitoring to be done as part of the investigational use of the product(s).

应以试验用药品及其相关产品在以往的研究中所得出的经验为基础，在 IB 中提供使用试验药品的可能出现的危险及药品不良反应的描述。同时亦应提供在试验用药品的研究应用中所应采取的预防措施和特殊的监护手段的描述。

c) Marketing Experience

市场经验

The IB should identify countries where the investigational product has been marketed or approved. Any significant information arising from the marketed use should be summarised (e.g., formulations, dosages, routes of administration, and adverse product reactions). The IB should also identify all the countries where the investigational product did not receive approval/registration for marketing or was withdrawn from marketing/registration.

IB 应当识别试验用药品已经上市或已经批准的国家。从上市使用中得到的任何重要资料应当摘要陈述（如处方、剂量、给药途径和药品不良反应）。IB 也应当识别试验用药品还没有得到批准/注册上市或退出上市/注册的所有国家。

7.3.7 Summary of Data and Guidance for the Investigator

资料概要及研究者指南

This section should provide an overall discussion of the nonclinical and clinical data, and should summarise the information from various sources on different aspects of the investigational product(s), wherever possible. In this way, the investigator can be provided with the most informative interpretation of the available data and with an assessment of the implications of the information for future clinical trials.

本部分应当提供一个非临床和临床数据的全面讨论，只要可能，对试验用药品不同方面的各种来源的资料作一摘要。这样，研究者可以得到现有数据的最见闻博广的解释，和这些资料对于将来临床试验意义的评价。

Where appropriate, the published reports on related products should be discussed. This could help the investigator to anticipate adverse drug reactions or other problems in clinical trials.

如有必要，应对有关产品已发表的报告进行讨论。这有助于研究者在实施临床试验的过程中预料药品不良反应或其他可能出现的问题。

The overall aim of this section is to provide the investigator with a clear understanding of the possible risks and adverse reactions, and of the specific tests, observations, and precautions that may be needed for a clinical trial. This understanding should be based on the available physical, chemical, pharmaceutical, pharmacological, toxicological, and clinical information on the investigational product(s). Guidance should also be provided to the clinical investigator on the recognition and treatment of possible overdose and adverse drug reactions that is based on previous human experience and on the pharmacology of the investigational product.

本部分的目的是让研究者对可能的风险和不良反应，以及临床试验中可能需要的特殊监察、观察资料和防范措施有明确的了解。这种了解应当以关于研究该药物的物理、化学、药学、药理、毒理和临床资料为基础。根据以往人类的经验和试验用药品的药理学，指南也应向临床研究者提供可能发生的药物过量和药品不良反应的认识及治疗方面的指导。

7.4 APPENDIX 1: 附录 1

TITLE PAGE (*Example*) 标题页
SPONSOR'S NAME 申办者名称

Product: 产品名
Research Number: 研究编号
Name(s): Chemical 名称：化学名
Generic (if approved) 通用名（如已获批准）
Trade Name(s) (if legally permissible and desired by the sponsor) 商品名（如合法且申办者希望采用）

INVESTIGATOR'S BROCHURE 研究者手册

Edition Number: 版本号
Release Date:发行日期

Replaces Previous Edition Number: 替代的前版本编号

Date: 日期

7.5 APPENDIX 2: 附录 2

TABLE OF CONTENTS OF INVESTIGATOR'S BROCHURE (*Example*)
IB 目录（举例）

8. ESSENTIAL DOCUMENTS FOR THE CONDUCT OF A CLINICAL TRIAL 临床试验必需文件

8.1 Introduction 引言

Essential Documents are those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements.

必需文件是指那些可单独和合起来用于评价试验的实施及所产生的数据质量的文件。这些文件反映研究者、申办者和监察员对 GCP 和所有的现行管理要求的依从性。

Essential Documents also serve a number of other important purposes. Filing essential documents at the investigator/institution and sponsor sites in a timely manner can greatly assist in the successful management of a trial by the investigator, sponsor and monitor. These documents are also the ones which are usually audited by the sponsor's independent audit function and inspected by the regulatory authority (ies) as part of the process to confirm the validity of the trial conduct and the integrity of data collected.

必需文件也用于其他一些目的。在研究者/研究机构和申办者驻地现场及时的将必需文件归档，能够极大地帮助研究者、申办者和监察员对试验进行成功的管理。作为确认试验实施的有效性和所收集数据完整性的过程的一部分，这些文件也经常受申办者委派的独立稽查员稽查并接收管理当局视察。

The minimum list of essential documents which has been developed follows. The various documents are grouped in three sections according to the stage of the trial during which they will normally be generated: 1) before the clinical phase of the trial commences, 2) during the clinical conduct of the trial, and 3) after completion or termination of the trial. A description is given of the purpose of each document, and whether it should be filed in either the investigator/institution or sponsor files, or both. It is acceptable to combine some of the documents, provided the individual elements are readily identifiable.

下面简要列出最低限度的必需文件。根据其在试验的不同阶段的征程产生，可将不同文件分为三个部分：(1)在临床试验开始之前；(2)临床试验进行期间；(3)完成或终止临床试验后。每一文件都要说明其目的，以及是否将该文件列入研究者/研究机构或申办者或双方的档案中。如果每个部分都易于辨认的，那么将一些文件合并也是可以接受的。

Trial master files should be established at the beginning of the trial, both at the investigator/institution’s site and at the sponsor's office. A final close-out of a trial can only be done when the monitor has reviewed both investigator/institution and sponsor files and confirmed that all necessary documents are in the

appropriate files.

试验开始时，在研究者/研究机构驻地及申办者办公室都该建立试验总档案。只有当监查员审核了研究者/研究机构及申办者双方的档案并确定所有必要的文件都在适宜的档案卷宗内，试验才能最后结束。

Any or all of the documents addressed in this guideline may be subject to, and should be available for, audit by the sponsor's auditor and inspection by the regulatory authority(ies).

在该指导原则内提及的任何或所有文件可能受到，也应当提供让申办者方稽查员的稽查和主管部门的视察。

8.2 Before the Clinical Phase of the Trial Commences 临床试验开始前

During this planning stage the following documents should be generated and should be on file before the trial formally starts .

在指定研究计划阶段，应产生下列文件并在试验正式开始之前归档。

	Title of Document 文件标题	Purpose 目的	Located in Files of 归档在	
			Investigator/Institution 研究者/ 研究机构	**Sponsor** 申办者
8.2.1	**INVESTIGATORI'S BROCHURE** 研究者手册	To document that relevant and current scientific information about the investigational product has been provided to the investigator 证明有关试验药品的相关信息和最新科研动态已经提供给研究者	X	X
8.2.2	**SIGNED PROTOCOL AND AMENDMENTS, IF ANY, AND SAMPLE CASE REPORT FORM (CRF)** 已签字的试验方案和修改(若有)及病例报告表(CRF)样本	To document investigator and sponsor agreement to the protocol/amendment(s) and CRF 证明研究者和申办者同意试验方案/修改和 CRF	X	X
8.2.3	**INFORMATION GIVEN TO TRIAL SUBJECT** 受试对象应知信息 **INFORMED CONSENT FORM** (including all applicable translations) 一知情同意书（包括所有实用的译文 **-ANY OTHER WRITTEN INFORMATION** 一任何其他书面信息 **-ADVERTISEMENT FOR SUBJECT ECRUITMENT (if used)** 一招募对象的广告（若使用）	To document the informed consent 证明知情同意 To document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent 证明受试对象获得恰当的书面信息（内容及措辞）以支持他们提供完全知情同意的能力 To document that recruitment measures are appropriate and not coercive 证明招募手段是合宜的且无胁迫嫌疑	X X X	X X X
8.2.4	**FINANCIAL ASPECTS OF THE TRIA 试验的财务状况**	To document the financial agreement between the investigator/institution and the sponsor for the trial 记录研究者/研究机构和申办者之间关于试验的财务协议	X	X
8.2.5	**INSURANCE STATEMEN** **（where required）** 保险陈述（必要时）	To document that compensation to subject(s) for trial-related injury will be available 证明受试对象遭受与试验相关伤害时将获得补偿	X	X

8.2.6	**SIGNEDAGREEMENT BETWEEN INVOLVED PARTIES, e.g.:** 参与试验各方之间签署的协议，例如： - investigator/institution and sponsor －研究者/研究机构和申办者 - investigator/institution and CRO －研究者/研究机构和 CRO - sponsor and CRO －申办者和 CRO - investigator/institution and authority(ies) (where equired) －研究者/研究机构和主管部门（必要时）	To document agreements 证明一致同意	X X X	X X(where required，需要时) X X
8.2.7	**DATED,DOCUMENTED APPROVAL / FAVOURABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB) /INDEPENDENT ETHICS COMMITTEE (IEC) OF THE FOLLOWING:** IRB/IEC 对以下各项内容的书面批准/赞成意见并注明日期 - protocol and any amendments －试验方案和任何修改 - CRF (if applicable) －CRF(如适用) - informed consent form(s) －知情同意书 - any other written information to be provided to the subject(s) －任何其他提供给受试对象的书面资料 - advertisement for subject recruitment (if used)	To document that the trial has been subject to IRB/IEC review and given approval/favourable opinion. To identify the version number and date of the document(s) 证明试验已经过 IRB/IEC 评估并获得批准/赞成意见。确认文件的版本编号和形成日期	X	X

	一招募志愿者广告（若使用） - subject compensation (if any) 一对受试对象的补偿（若有） - any other documents given approval/ favourable opinion一任何其他获得批准/赞成意见的文件			
8.2.8	**INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE COMPOSITION** IRB/IEC 的组成	To document that the IRB/IEC is constituted in agreement with GCP 证明 IRB/IEC 的组成符合 GCP 要求	X	X(必要时)
8.2.9	**AUTHORISATION/APPROVAL/ NOTIFICATION OF PROTOCOL** (where required)主管部门对试验方案的认可/批准/通报（必要时）	To document appropriate authorisation/approval/notification by the regulatory authority(ies) has been obtained prior to initiation of the trial in compliance with the applicable regulatory requirement(s)证明在试验开始之前已经按照现行的管理要求获得了主管部门适宜的任何/批准/通报	X(必要时)	X(必要时)
8.2.10	**CURRICULUM VITAE AND/OR OTHER RELEVANT DOCUMENTS EVIDENCING QUALIFICATIONS OF INVESTIGATOR(S) AND SUB-INVESTIGATOR(S)** 研究者和次级研究人员履历和/或证明其资格的其他相关文件	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects 证明有资格并适合执行试验和/或为受试对象提供医疗指导	X	X
8.2.11	**NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/ LABORATORY/TECHNICAL PROCEDURE(S) AND/OR TEST(S) INCLUDED IN THE PROTOCOL** 试验方案中涉及的医学/实验室/技术程序和/或测试的正常值和/或正常范围	To document normal values and/or ranges of the tests 记录各项测试的正常值和/或正常范围	X	X
8.2.12	**MEDICAL/LABORATORY/TECHNICAL PROCEDURES /TEST** 医疗/实验室/技术程序/测试 - certification or	To document competence of facility to perform required test(s) , and support reliability of results 证明研究设备完成所需要测试项目的能力，支持研究结果的可靠性	X（必要时）	X

	一资格证明，或 - accreditation or 一认可证明，或 - established quality control and/or external quality assessment or 一已建立的质量控制和/或外部质量评价，或 - other validation (where required)一其他验证体系（必要时）			
8.2.13	**SAMPLE OF LABEL(S) ATTACHED TO INVESTIGATIONAL PRODUCT CONTAINER(S)** 研究药物容器标签样本	To document compliance with applicable labelling regulations and appropriateness of instructions provided to the subjects 证明对现行标签规定的依从性及提供给受试对象的用法说明书的适宜性		X
8.2.14	**INSTRUCTIONS FOR HANDLING OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS**(if not included in protocol or Investigator's Brochure) 研究药物及试验相关材料（如果在试验方案或研究者手册没有提及）传递指南	To document instructions needed to ensure proper storage, packaging, dispensing and disposition of investigational products and trial-related materials 记录确保研究药物和试验相关材料被恰当贮存、包装、分发和处置的指导原则	X	X
8.2.15	**SHIPPING RECORDS FOR INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS** 研究药物及试验相关材料的物理运送	To document shipment dates, batch numbers and method of shipment of investigational product(s) and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability 证明研究药物及试验相关材料的运送日期、批号和运送方法。允许追踪药物批号、运送条件状况和责任	X	X
8.2.16	**CERTIFICATE(S) OF ANALYSIS OF INVESTIGATIONAL PRODUCT(S) SHIPPED** 所运送的研究药物的分析证明	To document identity, purity, and strength of investigational product(s) to be used in the trial 证明用于试验的研究药物的成分、纯度和浓度		X
8.2.17	**DECODING PROCEDURES FOR BLINDED TRIALS** 盲法试验的解码程序	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the	X	X(若可行应有第三方)

		blind for the remaining subjects' treatment 说明在紧急状况下，如何揭示加盲研究药物的身份而不使其余受试对象的治疗破盲		
8.2.18	**MASTER RANDOMISATION LIST** 总随机表	To document method for randomisation of trial population 证明受试人群的随机化方法		X(若可行应有第三方)
8.2.19	**PRE-TRIAL MONITORING REPORT** 试验前监察报告	To document that the site is suitable for the trial (may be combined with 8.2.20) 证明试验场所适于开展试验（可与 8.2.20 合并）		X
8.2.20	**TRIAL INITIATION MONITORING REPORT** 试验开始的监察报告	To document that trial procedures were reviewed with the investigator and the investigator's trial staff (may be combined with 8.2.19)证明研究者及研究小组成员已评估了试验程序（可与 8.2.19 合并）	X	X

8.3 During the Clinical Conduct of the Trial

临床试验进行期间

In addition to having on file the above documents, the following should be added to the files during the trial as evidence that all new relevant information is documented as it becomes available

除了上述文件应归档外，在试验进行过程中，下述文件也应添加到档案中以证明所有获得的新的相关资料都记录在案。

8.3.1	**INVESTIGATOR'S BROCHURE UPDATES** 更新的研究者手册	To document that investigator is informed in a timely manner of relevant information as it becomes available 证明所获得的相关信息被及时反馈给研究者	X	X
8.3.2	**ANY REVISION TO:** 对下列内容任何的更改： - protocol/amendment(s) and CRF －试验方案/修改和 CRF - informed consent form －知情同意书 - any other written information provided to subjects －任何提供给受试对象的书面资料	To document revisions of these trial related documents that take effect during trial 记录对这些试验相关文件的修改，这些改变在试验期间生效	X	X

	- advertisement for subject recruitment (*if used*) －招募受试对象的广告（若使用）			
8.3.3	**DATED, DOCUMENTED APPROVAL/FAVOURABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB) /INDEPENDENT ETHICS COMMITTEE (IEC) OF THE FOLLOWING:** －IRB/IEC 对以下各项内容的书面批准/赞成意见（注明日期） - protocol amendment(s) －试验方案修改 - revision(s) of: －下列文件修订本 - informed consent form －知情同意书 - any other written information to be provided to the subject－任何其他提供给受试对象的书面资料 -advertisement for subject recruitment (if used) －招募志愿者广告（若使用） - any other documents given approval/favourable opinion －任何其他获得批准/赞成意见的文件 - continuing review of trial (where required) －对试验的持续审评（必要时）	o document that the amendment(s) and/or revision(s) have been subject to IRB/IEC review and were given approval/favourable opinion. To identify the version number and date of the document(s). 证明这些修改和修订都经过 IRB/IEC 的审评并获得批准/赞成意见。确认记录的版本的编号和日期	X	X
8.3.4	**REGULATORY AUTHORITY(IES)**	To document compliance with applicable regulatory	X（必要时）	X

	AUTHORISATIONS/APPROVALS/NOTIFICATIONS WHERE REQUIRED FOR: 必要时管理当局对下列内容的认可/批准/通报 - protocol amendment(s) and other documents －试验方案修改及其他文件	requirements 证明符合现行管理要求		
8.3.5	**CURRICULUM VITAE FOR NEW INVESTIGATOR(S) AND/OR SUB-INVESTIGATOR(S)** 新的研究者和/或次级研究人员的履历	(see 8.2.10)（见 8.2.10）	X	X
8.3.6	**UPDATES TO NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/ LABORATORY/ TECHNICAL PROCEDURE(S)/TEST(S) INCLUDED IN THE PROTOCOL** 试验方案中涉及的医学/实验室/技术程序和/或测试的正常值范围的更新	To document normal values and ranges that are revised during the trial (see 8.2.11) 记录在试验期间修订的正常值和正常范围（见 8.2.11）	X	X
8.3.7	**UPDATES OF MEDICAL/LABORATORY/ TECHNICAL PROCEDURES/TESTS** 医学/实验室/技术程序和/测试的更新 - certification or －资格证明，或 - accreditation or －认可证明，或 - established quality control and/or external quality assessment or －已建立的质量控制和/或外部质量评价，或 - other validation (where required) －其他验证体系（必要时）	To document that tests remain adequate throughout the trial period (see 8.2.12) 证明在整个试验期间各项测试都是符合要求的（见 8.2.12）	X（必要时）	X
8.3.8	**DOCUMENTATION OF INVESTIGATIONAL**	（见 8.2.15）	X	X

	PRODUCT(S) AND TRIAL-RELATED MATERIALS SHIPMENT 研究药物及试验相关材料运送记录			
8.3.9	**CERTIFICATE(S) OF ANALYSIS FOR NEW BATCHES OF INVESTIGATIONAL PRODUCTS** 新批次研究药物的分析证明	（见 8.2.16）		X
8.3.10	**MONITORING VISIT REPORTS** 监察随访报告	To document site visits by, and findings of, the monitor 记录监察员的现场访问及结论		X
8.3.11	**RELEVANT COMMUNICATIONS OTHER THAN SITE VISITS** 现场访问之外的相关通讯联络记录 **- letters** －信件 - meeting notes －会议记录 –notes of telephone calls －电话记录	To document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event (AE) reporting 记录关于试验管理、违背试验方案、试验实施、不良事件（ＡＥ）报告等方面的协议或重要讨论	X	X
8.3.12	**SIGNED INFORMED CONSENT FORMS** 署名的知情同意书	To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each subject in trial. Also to document direct access permission (see 8.2.3) 证明知情同意遵照 GCP 和试验方案在每一受试对象参加研究之前获得；并证明受试对象对直接访问数据的许可（见 8.2.3）	X	
8.3.13	**SOURCE DOCUMENTS** 原始记录源文件	To document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of subject 记录受试对象的状态，证明所收集试验数据的完整性。包括与试验和医学治疗有关的原始文件以及受试对象的病史记录	X	
8.3.14	**CASE REPORT FORMS (CRF)**已签字、注明日期	To document that the investigator or authorised member of the	X(copy)	X (originanl)

	且完整的病例记录表（CRF）	investigator's staff confirms the observations recorded 证明研究者或授权的研究小组成员确认所记录的观测值	X(复印件)	X(原件)
8.3.15	**DOCUMENTATION OF CRF CORRECTIONS** CRF 更正记录	To document all changes/additions or corrections made to CRF after initial data were recorded 证明获得初始数据记录后对 CRF 的所有更改/补充或更正	X(复印件)	X(原件)
8.3.16	**NOTIFICATION BY ORIGINATING INVESTIGATOR TO SPONSOR OF SERIOUS ADVERSE EVENTS AND RELATED REPORTS** 一线研究者向申办者通报有关严重不良事件及相关报告	Notification by originating investigator to sponsor of serious adverse events and related reports in accordance with 4.11 一线研究者根据 4.11 向申办者通报严重不良事件及相关报告	X	X
8.3.17	**NOTIFICATION BY SPONSOR AND/OR INVESTIGATOR, WHERE APPLICABLE, TO REGULATORY AUTHORITY(IES) AND IRB(S)/IEC(S) OF UNEXPECTED SERIOUS ADVERSE DRUG REACTIONS AND OF OTHER SAFETY INFORMATION** 申办者和/或研究者向主管部门和 IRB/IEC 提交的非预期的药物严重不良反应及其他安全性资料	Notification by sponsor and/or investigator, where applicable, to regulatory authorities and IRB(s)/IEC(s) of unexpected serious adverse drug reactions in accordance with 5.17 and 4.11.1 and of other safety information in accordance with 5.16.2 申办者和/或研究者向主管部门和 IRB/IEC 通报非预期的药物严重不良反应（根据 5.17 和 4.11.1）及其他安全性资料（根据 5.16.2 和 4.11.2）	X（必要时）	X
8.3.18	**NOTIFICATION BY SPONSOR TO INVESTIGATORS OF SAFETY INFORMATION** 申办者向研究者通报的安全性资料	Notification by sponsor to investigators of safety information in accordance with 5.16.2 申办者根据 5.16.2 向研究者通报安全性资料	X	X
8.3.19	**INTERIM OR ANNUAL REPORTS TO IRB/IEC AND AUTHORITY(IES)**向 IRB/IEC 和主管部门提交的中期报告或年度报告	Interim or annual reports provided to IRB/IEC in accordance with 4.10 and to authority(ies) in accordance with 5.17.3 分别根据 4.1 和 5.17.3 向 IRB/IEC 和管理当局提交中期报告或年度报告	X	X（必要时）
8.3.20	**SUBJECT SCREENING LOG** 受试对象筛选记录	To document identification of subjects who entered pre-trial screening 记录进入试验前筛选程序的受试对象的身份证明	X	X（必要时）
8.3.21	**SUBJECT IDENTIFICATION CODE LIST** 受试对象身份证明编码表	To document that investigator/institution keeps a confidential list of names of all subjects allocated to trial numbers on enrolling in the trial. Allows investigator/institution to reveal	X	

		identity of any subject 研究人员/研究机构保存得一份被招募进入试验并获得试验号码得所有受试对象姓名得保密名单		
8.3.22	**SUBJECT ENROLMENT LOG** 受试对象招募日志	To document chronological enrolment of subjects by trial number 记录按试验流水号根据时间顺序招募试验对象	X	
8.3.23	**INVESTIGATIONAL PRODUCTS ACCOUNTABILITY AT THE SITE** 研究药物在试验点的可计数性	To document that investigational product(s) have been used according to the protocol 证明试验药品是按咋后试验方案使用的	X	X
8.3.24	**SIGNATURE SHEET** 签字页	To document signatures and initials of all persons authorised to make entries and/or corrections on CRFs 记录所有授权在 CRF 上进行数据登录和/或更正的人员的签名及姓名首字母	X	X
8.3.25	**RECORD OF RETAINED BODY FLUIDS/ TISSUE sample(if any)** 保存体液/组织样本的记录（若有）	To document location and identification of retained samples if assays need to be repeated 记录如果需重复分析时保留样本的存放位置和标识	X	X

8.4 After Completion or Termination of the Trial

临床试验完成或终止之后

After completion or termination of the trial, all of the documents identified in sections 8.2 and 8.3 should be in the file together with the following 在试验完成或中止之后，8.2 及 8.3 节所列文件及下列文件皆应归档。

8.4.1	**INVESTIGATIONAL PRODUCT(S) ACCOUNTABILITY AT SITE** 试验药品在试验点的可计数性	To document that the investigational product(s) have been used according to the protocol. To documents the final accounting of investigational product(s) received at the site, dispensed to subjects, returned by the subjects, and returned to sponsor 证明试验药品是根据试验方案使用。证明在研究现场收到的、发放给受试对象的、受试对象送还的、返还给申办者的试验药品的最后计数	X	X
8.4.2	**DOCUMENTATION OF INVESTIGATIONAL PRODUCT DESTRUCTION** 试验药品销毁记录	To document destruction of unused investigational products by sponsor or at site 证明未被使用的试验药品由申办者或在研究现场销毁的情况	X（if destroyed at site 若在研究现场销毁的话）	X
8.4.3	**COMPLETED SUBJECT IDENTIFICATION CODE**	To permit identification of all subjects enrolled in the trial in	X	

	LIST 完整的受试对象身份鉴别编码表	case follow-up is required. List should be kept in a confidential manner and for agreed upon time 在需要随访时允许鉴别被招募进入试验的所有受试对象的身份。编码表必需保密并存放至约定时间		
8.4.4	**AUDIT CERTIFICATE (if available)**稽查证明（如需要）	To document that audit was performed 证明已进行过稽查		X
8.4.5	**FINAL TRIAL CLOSE-OUT MONITORING REPORT** 试验结束监察报告	To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files 证明所有试验结束所必需的活动都已完成，必需文件的副本保存在合适的档案中		X
8.4.6	**TREATMENT ALLOCATION AND DECODING DOCUMENTATION** 治疗分配表及解码记录	Returned to sponsor to document any decoding that may have occurred 返还给申办者以证明任何发生过的解码操作		X
8.4.7	**FINAL REPORT BY INVESTIGATOR TO IRB/IEC WHERE REQUIRED, AND WHERE APPLICABLE, TO THE REGULATORY AUTHORITY(IES)** 必要时研究者向 IRB/IEC 及合适时向主管部门提交的总结报告	To document completion of the trial 证明试验的完成	X	X
8.4.8	**CLINICAL STUDY REPORT** 临床研究报告	To document results and interpretation of trial 提供试验的结果和解释	X（if applicable 如合适）	X