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国际医疗器械监管机构论坛

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Preface/前言

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world.
本文件由国际医疗器械监管机构论坛（IMDRF）制定，是一个由全球医疗器械监管机构自愿组成的团体。

1 Introduction\引言

What is clinical evaluation? / 何为临床评价？

Clinical evaluation is a set of ongoing activities that use scientifically sound methods for the assessment and analysis of clinical data to verify the safety, clinical performance and/or effectiveness of the device when used as intended by the manufacturer.
临床评价是采用科学合理的方法评价并分析临床数据，以验证器械在生产商宣称的预期使用下的安全性、临床性能和／或有效性的一套持续开展的活动。

When is clinical evaluation undertaken? / 何时开展临床评价？

Clinical evaluation is an ongoing process conducted throughout the life cycle of a medical device. It is first performed during the development of a medical device in order to identify data that need to be generated for regulatory purposes and will inform if a new device clinical investigation is necessary, together with the outcomes which need to be studied. It is then repeated periodically as new safety, clinical performance, and/or effectiveness information about the device is obtained during its use. This information is fed into the ongoing risk management process (according to ISO 14971:2007) and may result in changes to the manufacturer's risk assessment, Instructions for Use and post market activities.
临床评价是贯穿于医疗器械整个生命周期的一个持续的过程。首先，临床评价在医疗器械开发阶段开展，旨在识别为满足监管目的所需要生成的数据，并确定是否需要开展新的器械临床试验以及明确需要研究的结果。然后，随着在使用过程中不断获得有关该器械的新的安全性、临床性能和／或有效性信息，对其定期进行重复评价。此信息将输入持续的风险管理过程（根据 ISO14971:2007）并可能导致对生产商风险评定、使用说明书和上市后活动的更改。

Why is clinical evaluation important? / 为什么临床评价是非常重要的？

When placing a medical device on the market the manufacturer must have demonstrated through the use of appropriate conformity assessment procedures that the device complies with the Essential Principles of Safety and Performance of Medical Devices (the Essential Principles). Generally, from a clinical perspective, it is expected that the manufacturer has demonstrated the device achieves its intended performance during normal conditions of use and that the known, and foreseeable risks are minimised and acceptable when weighed against the benefits of the intended performance, and that any claims made about the device's safety, clinical performance and/or effectiveness (e.g. product labelling and instructions for use) are supported by suitable evidence.
当医疗器械申请上市时，生产商必须通过适当的符合性评估程序证明器械符合《医疗器械安全性与性能基本原则》（基本原则）。通常情况下，从临床的角度考虑，预期生产商已经证明：在正常的使用条件下，该器械达到了预期的性能；而且在与预期性能的受益进行比较时，已知的、可预见的风险是已降至最低并可接受的；对该器械的安全性、临床性能

和／或有效性（例如产品标签与使用说明书）的任何宣称均得到适当证据的支持。

With regard to post market activities, manufacturers are expected to implement and maintain surveillance programs that routinely monitor the safety, clinical performance and/or effectiveness of the device as part of their Quality Management System. The scope and nature of such post market surveillance should be appropriate to the device and its intended use. Using data generated from such programs (e.g. safety reports, including adverse event reports; results from published literature, any further clinical investigations and formal post market surveillance studies; etc), a manufacturer should periodically review performance, safety and the benefit-risk assessment for the device through a clinical evaluation, and update the clinical evidence accordingly. This ongoing clinical evaluation process should allow manufacturers to communicate with conformity assessment bodies and regulatory authorities in accordance with local reporting requirements any information that has an important bearing on the benefit-risk assessment of the device or that would indicate a need for labelling changes regarding contraindications, warnings, precautions or instructions for use etc.
考虑到上市后活动，预期生产商会执行并维持对医疗器械安全性、临床性能和／或有效性进行日常监视的监督项目，并将其作为质量管理体系的一部分。此类上市后监督的范围和性质应适用于该器械及其预期用途。利用该程序产生的数据（例如安全性报告，包括不良事件报告、出版文献中的结果、任何进一步的临床试验与正式的上市后监督研究等），生产商应该通过临床评价对器械的性能、安全性以及受益-风险评价进行定期审核，并相应更新其临床证据。这一持续的临床评价过程应允许生产商根据当地的报告要求，就那些对器械的受益-风险评估有重要意义、或者指示需要对禁忌、警告、防范措施或使用说明书等方面进行标签变更的任何信息，与符合性评价机构以及监管机构进行沟通。

What is the process? / 临床评价的程序是什么？

To conduct a clinical evaluation, a manufacturer needs to:
为进行临床评价，生产商需要：

- identify the Essential Principles that require support from relevant clinical data;
- 识别需要临床相关数据支持的基本原则；
- identify available clinical data relevant to the device and its intended use;
- 识别与器械及其预期用途相关的可用临床数据；
- evaluate (appraise and analyse) clinical data in terms of its suitability and contribution to demonstrating the safety, clinical performance, and/or effectiveness of the device in relation to its intended use;
- 根据对证明器械相关预期用途的下的安全性、临床性能、和／或有效性的适宜程度和贡献度，对临床数据进行评价（评估和分析）；
- generate clinical data needed to address remaining questions of safety, clinical performance, and/or effectiveness;
- 对需要解决的剩余安全性、临床性能、和／或有效性问题生成临床数据；
- bring all the clinical data together to reach conclusions about the safety, clinical performance, and/or effectiveness of the device.
- 汇集全部临床数据，达成关于器械安全性、临床性能、和／或有效性的结

论。

The results of this process are documented in a clinical evaluation report. The clinical evaluation report and the clinical data on which it is based serve as the clinical evidence that supports the marketing of the device.
此程序的结果将归档于临床评价报告。临床评价报告及作为其基础的临床数据将用作为支持器械上市的临床证据。

The clinical evidence, along with other design verification and validation documentation, device description, labelling, risk analysis and manufacturing information, is needed to allow a manufacturer to demonstrate conformity with the Essential Principles and is part of the technical documentation of a medical device.
生产商需要临床证据，会同其他设计验证和确认文件、器械描述、标签、风险分析以及生产信息以证明器械符合基本原则，并且这些信息是医疗器械技术文件的一部分。

How detailed should the clinical evaluation be? /临床评价详细程度应如何？

A clinical evaluation should be thorough and objective (i.e. it should consider both favourable and unfavourable data), with the intention of demonstrating valid clinical evidence of the safety clinical performance, and/or effectiveness of the device. However, it is important to recognise that there is considerable diversity in the types and history of technologies used in medical devices and the risks posed by them. Many devices are developed or modified by incremental innovation, so they are not completely novel. Thus, it is often possible to draw on the clinical experience and literature reports of the safety, clinical performance, and/or effectiveness of comparable devices to establish the clinical evidence, thereby reducing the need for clinical data generated through clinical investigation of the device in question. Similarly, it may be possible to use compliance with recognised standards to satisfy the clinical evidence requirements for devices based on technologies with well established safety, clinical performance, and/or effectiveness characteristics.
为了提供证明器械安全性、临床性能、和／或有效性的有效临床依据，临床评价应该全面和客观（即有利和不利两方面的数据都应当考虑到）。然而，我们必须认识到，医疗器械所用技术类型及其历史、以及所产生的风险存在着相当大的差异。许多器械是通过逐渐增长的革新方法开发或者改进的，因此并不完全是创新的。这样，就通常可以利用关于比较器械安全性、临床性能和／或有效性的临床经验和文献报告作为临床证据，因而降低了对评估器械开展临床研究以生成数据的需求。同样，对于采用安全性、临床性能和／或有效性特征均已得到充分验证的技术的器械，可以通过证明符合公认标准来满足临床证据要求。

The depth and extent of clinical evaluations should be flexible, not unduly burdensome, and appropriate to the nature, intended use and risks of the device in question. Therefore, this guidance is not intended to impose specific requirements.
对评估器械的临床评价的深度和广度应该具有灵活性，不应构成过度的负担，并与评估器械的性质、预期用途以及风险相适应。因此，本指南不会提出任何具体要求。

This document supersedes an earlier version produced under the Global Harmonization Task Force (GHTF) with the same title in May, 2007(GHTF/SG5/N2R8:2007).
本文件已取代全球协调工作组（GHTF）于 2007 年 5 月发布的既往版本同名文件（GHTF/SG5/N2R8:2007）。

2 Scope\范围

The primary purpose of this document is to provide manufacturers with guidance on how to conduct and document the clinical evaluation of a medical device as part of the conformity assessment procedure prior to placing a medical device on the market as well as to support its ongoing marketing. It is also intended to provide guidance to regulators and other stakeholders when assessing clinical evidence provided by manufacturers.
本文件的基本目的是：为申请医疗器械上市以及支持其持续上市，就生产商应如何在符合性评估程序中实施医疗器械临床评价并形成文件提供指导。同时，本文件还希望为监管机构及其他相关方提供关于评估生产商所提交临床证据的指导。

This document provides the following guidance:
本文件提供以下指导：

- general principles of clinical evaluation;
- 临床评价的基本原则；
- how to identify relevant clinical data to be used in a clinical evaluation;
- 如何识别用于临床评价的有关临床数据；
- how to appraise and integrate clinical data into a summary; and
- 如何评估临床数据并将其收集汇总；以及
- how to document a clinical evaluation in a clinical evaluation report.
- 如何将临床评价归档于临床评价报告。

The guidance contained within this document is intended to apply to medical devices generally and the device component of combination products. It is not intended to cover IVDDs.
包含在此文件中的指南适用于医疗器械以及组合产品的器械部分，但并不包括体外诊断器械（IVDDs）。

3 References/参考文献

IMDRF/GHTF final documents / IMDRF/GHTF 最终文件

GHTF SG1/ *N044:2008 Role of Standards in the Assessment of Medical Devices*
GHTF SG1/ *N044:2008 标准在医疗器械评估中的作用*

GHTF SG1/ N071:2012 *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic*

(IVD) Medical Device'
GHTF SG1/ N071:2012 *'医疗器械'和'体外诊断（IVD）医疗器械'的术语定义*

GHTF SG1/ N78:2012 *Principles of Conformity Assessment for Medical Devices*
GHTF SG1/ N78:2012 *医疗器械符合性评价原则*

IMDRF GRRP WG/N47 FINAL: 2018 *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*
IMDRF GRRPWG/N47 FINAL: 2018 *医疗器械及体外诊断（IVD）医疗器械安全性和性能基本原则*

IMDRF SaMD WG/N41:2017 *Software as a Medical Device (SaMD): Clinical Evaluation*
IMDRF SaMD WG/N41:2017 *独立医疗器械软件（SaMD）：临床评价*

IMDRF Registry WG/N33 FINAL: 2016 *Principles of International System of Registries Linked to Other Data Sources and Tools*
IMDRF Registry WG/N33 FINAL: 2016 *国际登记系统与其他数据源和工具相关联的原则*

IMDRF Registry WG/N42 FINAL: 2017 *Methodological Principles in the Use of International Medical Device Registry Data*
IMDRF Registry WG/N42 FINAL: 2017 *使用国际医疗器械登记数据的方法原则*

IMDRF Registry WG/N46 FINAL: 2018 *Tools for Assessing the Usability of Registries in Support of Regulatory Decision-Making*
IMDRF Registry WG/N46 FINAL: 2018 *登记系统用于支持监管决策的可用性评价工具*

GHTF SG1/N011 R20:2008 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)*
GHTF SG1/N011 R20:2008*证明符合医疗器械安全性与性能基本原则的汇总技术文件（STED）*

IMDRF MDCE WG (PD1)/N56 *Clinical Evidence – Key definitions and Concepts*
IMDRF MDCE WG (PD1)/N56 *临床证据–主要定义与概念*

International standards/国际标准

ISO 14971:2007 *Medical devices - Application of risk management to medical devices*
ISO 14971:2007 *医疗器械-风险管理对医疗器械的应用*

ISO 14155-1: 2011 *Clinical investigation of medical devices for human subjects — Good clinical practice*
ISO 14155-1: 2011 *适用于人类受试者的医疗器械临床试验—临床试验质量管理规范*

4 Definitions/定义

Adverse Event: Any untoward medical occurrence
不良事件： 任何异常的医疗事件。

Clinical Data: **S**afety, clinical performance and/or effectiveness information that is generated from the clinical use of a medical device.
临床数据： 在医疗器械临床使用中所产生的安全性、临床性能和／或有效性的信息。

Clinical Evaluation: A set of ongoing activities that use scientifically sound methods for the assessment and analysis of clinical data to verify the safety, clinical performance and/or effectiveness of the device when used as intended by the manufacturer.
临床评价： 采用科学合理的方法评价和分析临床数据以验证器械在生产商宣称的预期使用下的安全性、临床性能和／或有效性的一套持续开展的活动。

Clinical Evidence: The clinical data and the clinical evaluation report pertaining to a medical device.
临床证据： 与医疗器械相关的临床数据与临床评价报告。

Clinical Investigation: Any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety, clinical performance, and/or effectiveness of a medical device.
临床试验： 在一例或多例受试者中开展的，用于评价医疗器械安全性、临床性能、和/或有效性的任何系统性的试验或研究。

Clinical Investigation Plan: Document that states the rationale, objectives, design and pre-specified analyses, methodology, monitoring, conduct and record-keeping of the clinical investigation.
临床试验方案： 阐明临床试验的依据、目的、设计及预先设定的分析手段、方法学、监视、执行以及记录保存的文件。

Clinical Investigator: The individual responsible for the conduct of a clinical investigation who takes the clinical responsibility for the well-being of the subjects involved.
临床研究者： 负责对开展临床研究、所涉及受试者的利益承担临床责任的人员。

Clinical Performance: The ability of a medical device to achieve its intended purpose as claimed by the manufacturer.
临床性能： 医疗器械实现生产商宣称的预期目的的能力。

Effectiveness: The ability of a medical device to achieve clinical outcome(s) in its intended use as claimed by the manufacturer.
有效性： 医疗器械实现生产商宣称的预期用途下的临床结果的能力。

Safety: Acceptable risks as weighed against benefits, when using the device according to the manufacturer's Instructions for Use.

安全性： 在根据生产商使用说明书使用器械时，与受益相比，风险可接受

Comparable Device: A medical device with related function chosen by the manufacturer to inform the clinical evaluation of the device in question.

比较器械： 由生产商根据该器械相关功能所选择的，旨在将其信息用于支持拟评价器械的临床评价医疗器械，

Conformity Assessment: The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Regulatory Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the *Essential Principles of Safety and Performance for Medical Devices and IVD Medical Device* (IMDRF GRRP WG/N47 FINAL: 2018).

符合性评价： 由生产商开展的，通过对按照监管机构的要求所生成的证据和过程进行系统性检查，以确定医疗器械是否具有生产商预期的安全性及性能，且因此符合*医疗器械及 IVD 器械安全性和性能基本原则* (IMDRF GRRP WG/N47 FINAL:2018)。

Intended Use / Purpose: The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

预期用途 / 目的： 反映在生产商所提供的规格、使用说明和相关信息中的，生产商关于产品使用、过程或服务的客观预期。

Serious Adverse Event: An adverse event that

严重不良事件： 指以下不良事件：

1. led to a death;
1. 导致死亡；
2. led to a serious deterioration in health that
2.导致健康的严重恶化：
    a. results in a life-threatening illness or injury;
    a.造成危及生命的疾病或者伤害；
    b. results in a permanent impairment of a body structure or body function;
    b.造成人体结构或者人体功能的永久性损害；
    c. requires inpatient hospitalisation or prolongation of existing hospitalisation
    c.要求患者实施住院治疗或者延长现有的住院时间
    d. results in medical or surgical intervention to prevent permanent impairment to body structure or a body function;

d.造成医疗或者外科干预，以防止人体结构或者人体功能的永久性损害；

e. led to foetal distress, foetal death or a congenital abnormality/ birth defect.

e.导致胎儿情况不稳定、胎儿死亡、先天畸形／出生缺陷。

Recognised Standards: Standards deemed to offer the presumption of conformity to specific essential principles of safety and performance. (SG1/ N044:2008)

公认标准： 视为可以为器械符合特定安全性与性能基本原则提供推测依据的标准。（SG1/ N044:2008）

Technical Documentation: The documented evidence, normally an output of the quality management system, that demonstrates compliance of a device to the *Essential Principles of Safety and Performance of Medical Devices* (IMDRF GRRP WG/N47 FINAL: 2018).

技术文档： 文档化证据，通常为质量管理体系的输出，证明该器械符合*《医疗器械安全性与性能基本原则》*（IMDRF GRRP WG/N47 FINAL: 2018）。

5 General principles of clinical evaluation/ 临床评价的基本原则

What is the scope of a clinical evaluation? / 临床评价的范围是什么？

The clinical evaluation is based on a comprehensive analysis of available pre- and post market clinical data relevant to the intended use of the device in question, including clinical performance data and safety data. This includes data specific to the device in question as well as any data relating to devices claimed as comparable by the manufacturer.
临床评价基于对拟评价器械预期用途相关的可用上市前和上市后临床数据（包括临床性能数据和安全性数据）进行的综合分析。其中包括拟评价器械特有的数据以及生产商所宣称的对比器械的任何相关数据。

The evaluation must also address any clinical claims made about the device, the adequacy of product labelling and product information (particularly contraindications, precautions/warnings), and the suitability of instructions for use.
评价必须对与器械相关的所有临床宣称、产品标签与产品信息的充分性（特别是禁忌、防范措施／警告）以及使用说明书的适宜性进行确认。

Before a clinical evaluation is undertaken the manufacturer should define its scope, based on the Essential Principles that need to be addressed from a clinical perspective. Considerations should include:
在临床评价开展之前，生产商应从临床角度，根据需要确认的基本原则内容规定其范围。应当考虑的内容包括：

- whether there are any design features of the device or target treatment populations that require specific attention.
- 器械是否存在需要特别关注的任何设计特征或者目标治疗人群。

The clinical evaluation should cover any design features that pose special performance or safety concerns (e.g. presence of medicinal, human or animal components), the intended purpose and application of the device (e.g. target treatment group and disease, proposed warnings, contraindications and method of application) and the specific claims made by the manufacturer about the safety, clinical performance and/or effectiveness of the device. The scope of the clinical evaluation will need to be informed by and cross referenced to the manufacturer's risk management documents. The risk management documents are expected to identify the risks associated with the device and how such risks have been addressed. The clinical evaluation is expected to address the significance of any risks that remain after design risk mitigation strategies have been employed by the manufacturer;
临床评价应包括会引起特殊性能或安全性方面关注因素的所有设计特征（例如存在药物、人源或者动物成分）、器械的预期目的和应用（例如目标治疗人群、疾病、提出的警告、禁忌以及应用方法）以及生产商就器械的安全性、临床性能和／或有效性所作的特定声明。需要指明临床评价的范围并交叉参考生产商的风险管理文件。该风险管理文件预期能够确定与器械有关的风险以及该风险是如何产生的。临床评价预期要关注那些在生产商采用设计风险缓解策略之后所留下的任何风险的严重性；

- whether data from comparable devices can be used to support the safety, clinical performance and/or effectiveness of the device in question.
- 来源于对比器械的数据能否用来支持拟评价器械的安全性、临床性能和／或有效性。

Comparable devices should be considered with respect to relevant aspects including intended use, technical and/or biological characteristics to inform the clinical evaluation of the device. These characteristics should be broadly similar, but consideration must be given to how differences may affect the safety, clinical performance and/or effectiveness of the device. In some circumstances, these characteristics are similar to such an extent that there would be no clinically significant difference in the safety, clinical performance and/or effectiveness of the device. For example, *intended use* includes the clinical condition being treated, the severity and stage of disease, the site of application to/in the body and the patient population; the *technical characteristics* include the design, specifications, physiochemical properties including energy intensity, deployment methods, critical performance requirements, and principles of operation; and *biological characteristics* include biocompatibility of materials in contact with body fluids/tissues. Some additional considerations for comparability are given in Appendix A. The manufacturer is also expected to include the supporting non-clinical information within the technical documentation for the device and cite its location within the clinical evaluation report. (Note: the clinical evaluation is not intended to assess the technical and biological characteristics *per se*); and
应从预期用途、技术和／或生物学特征等相关方面考虑对比器械的信息是否可用于拟评价器械的临床评价。这些特征应具有广泛相似性，但必须考虑差异性可能对器械的安全

性、临床性能和／或有效性产生何种影响。在某些情况下，这些特征的相似程度应使器械间的安全性、临床性能和／或有效性不存在临床显著差异。例如，器械的*预期用途*包括治疗的临床状况、疾病的严重程度和阶段、人体应用部位和患者人群；器械的*技术特征*包括该器械的设计、规格、理化特性（包括能量强度）、配置方法、关键性能要求和工作原理；并且器械的*生物特征*包括该器械与人体体液／组织接触材料的生物相容性。附件 A 中给出了关于可比性的一些额外考虑事项。另外希望生产商将该器械技术文档中支持性的非临床信息纳入评价报告，并在评价报告中注明引用部分在技术文件中的位置。（备注：临床评价本身并不预期对技术和生物特征进行评价）；以及

- the data source(s) and type(s) of data to be used in the clinical evaluation.
- 用于临床评价的数据来源和数据类型

Manufacturers may be able to leverage existing information drawn from any one or combination of data sources set out in Section 6.0. Factors that should be considered when choosing the type of data to be used in the clinical evaluation include the design, intended use and risks of the device; the developmental context of the technology on which the device is based (new vs established technology); and, for established technology, the proposed clinical application of that technology. Clinical evaluation of medical devices that are based on existing, well- established technologies and intended for an established use of the technology is most likely to rely on compliance with recognised standards and/or literature review and/or clinical experience of comparable devices. High risk devices, those based on technologies where there is little or no experience, and those that extend the intended purpose of an existing technology (i.e. a new clinical use) are most likely to require clinical investigation data. The manufacturer will need to give consideration to the advantages and limitations of each data type.

生产商可能可以利用第 6.0 章中规定的任何一种或多种综合数据来源中的已有信息。在选择用于临床评价的数据类型时，应考虑的因素包括：器械的设计、预期用途以及风险；器械所依赖的技术的发展背景（新技术还是成熟技术）；以及，对于成熟技术，还应考虑已申报的该技术的临床应用。如果医疗器械是基于现有成熟技术并预期用于该技术的成熟应用，则其临床评价最有可能通过符合公认标准和／或文献综述和／或对比器械的临床经验来实施。如果是基于很少或者没有使用经验的技术的高风险器械，或者对现有技术的预期用途进行扩展（即新的临床使用）的器械，则很可能要求提供临床试验数据。生产商需要考虑每种数据类型的优势和局限性。

How is a clinical evaluation performed? / 如何进行临床评价？

Once the scope has been defined, there are three discrete stages in performing a clinical evaluation (Figure 1):

评价范围确定后，开展临床评价将进入以下三个独立的阶段，（见图 1）：

- identification of pertinent standards and clinical data;
- 识别有关的标准和临床数据；
- appraisal of each individual data set, in terms of its relevance, applicability, quality and clinical significance; and

- 对每一独立数据集按照其相关性、适用性、质量以及临床意义进行评估；以及
- analysis of the individual data sets, whereby conclusions are reached about the safety, clinical performance and/or effectiveness and presentational aspects (labelling, patient information and instructions for use) of the device.
- 对独立数据集进行分析，得出与器械安全性、临床性能和／或有效性以及信息方面（标签、患者须知以及使用说明）相关的结论。

Each of these stages is covered in separate sections later in this document.
上述的每一阶段将包括在本文的不同章节中。

At the end of the clinical evaluation a report is prepared and combined with the relevant clinical data to form the clinical evidence for the device. If the manufacturer concludes there is insufficient clinical evidence to be able to declare conformity with the Essential Principles, the manufacturer will need to generate additional data (e.g. conduct a clinical investigation, broaden the scope of literature searching) to address the deficiency. In this respect clinical evaluation can be an iterative process.
临床评价完成后，将编制报告并与有关临床数据一起形成该器械的临床证据。若生产商得出临床证据不足以宣称与基本原则的符合性的结论，则生产商需要生成新的数据新的数据（例如开展临床试验、扩大文献检索的范围），以弥补其不足。从这一方面而言，临床评价可以是一个反复的过程。

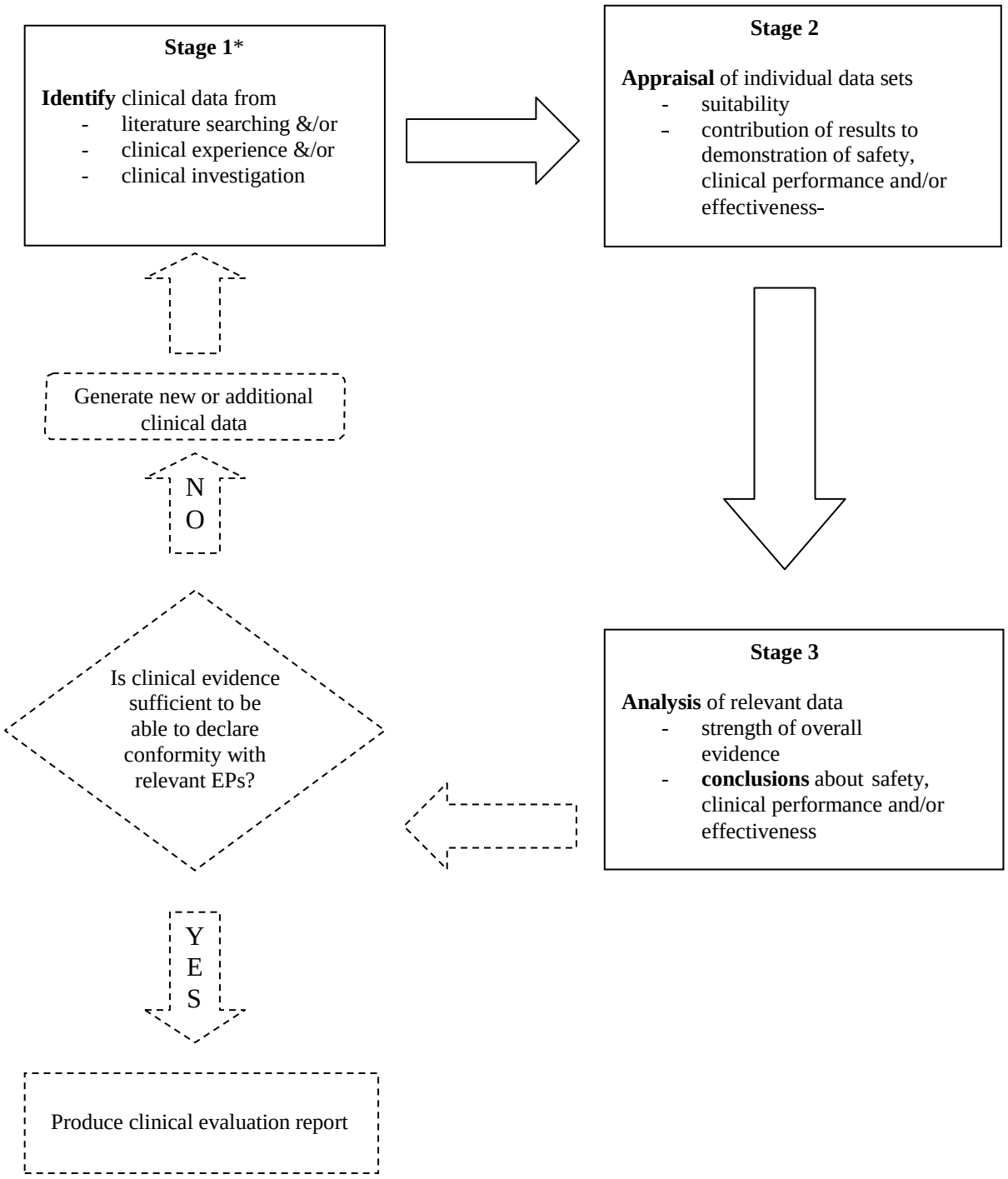
Who should perform the clinical evaluation? / 应当由谁来实施临床评价？

The clinical evaluation should be conducted by a suitably qualified individual or individuals. A manufacturer must be able to justify the choice of the evaluator(s) through reference to qualifications and documented experience.
临床评价应由具备适当资格的一名或多名人员开展。生产商必须能够通过资质鉴定以及有文件记录的经验来证明选择了正确的评价人员。

As a general principle, evaluators should possess knowledge of the following:
作为一般原则，评价人员应具备以下知识：

- the device technology and its application;
- 器械的技术以及其应用；
- research methodology (clinical investigation design and biostatistics); and
- 研究方法（临床研究设计和生物统计学）；和
- diagnosis and management of the conditions intended to be treated or diagnosed by the device.
- 器械预期治疗或诊断的情况的判断和管理。

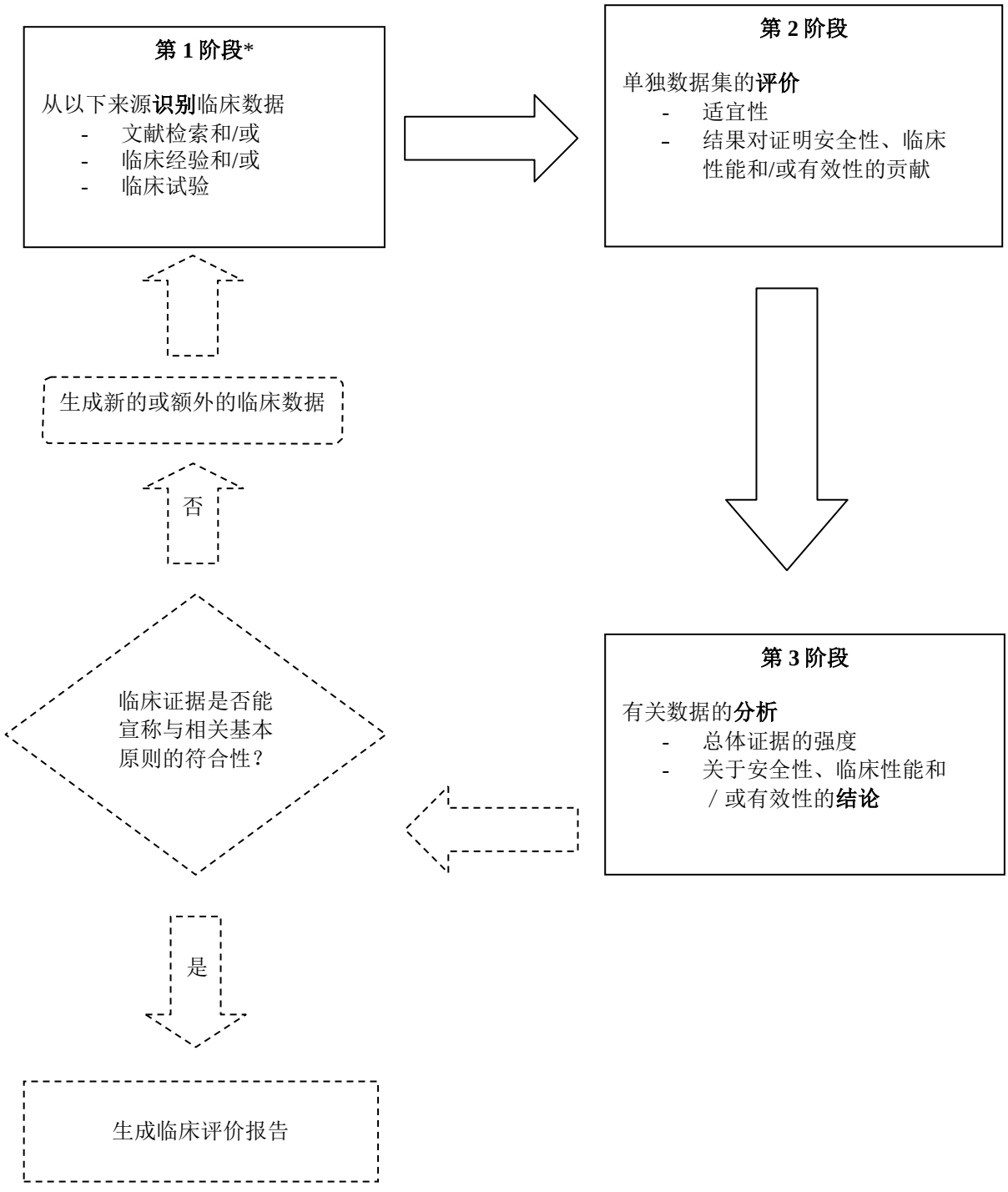
Figure 1 Stages of a Clinical Evaluation



EPs = Essential Principles of safety and performance of medical devices

* - Conformance to performance standards may be sufficient to demonstrate compliance to relevant Essential Principles

图 1 临床评价阶段



EPs=医疗器械安全性和性能基本原则

* -符合性能标准可能已足够证明符合相关的基本原则

What about in vitro diagnostic devices (IVDDs)? /体外诊断器械（IVDDs）应如何进行临床评价?

Clinical evaluation should be performed for in vitro diagnostic devices as part of conformity assessment to the Essential Principles in a manner similar to other devices. The basic principles of objective review of clinical data will apply as described in this guidance document. However, IVDDs offer some unique definitions and concepts, which have been defined in the GHTF/SG5/N6:2012: Clinical Evidence for IVD medical devices – Key Definitions and Concepts, as well as challenges in demonstrating clinical evidence and delineating when the elements of clinical evidence are appropriate for the IVDDs, which have been addressed in the GHTF/SG5/N7:2012: Clinical Evidence for IVD medical devices – Scientific Validity Determination and Performance Evaluation.
对于体外诊断器械的临床评价应该以与其他器械相似的方式，作为对基本原则要求的符合性评价的一部分。临床数据的客观审核基础原则将如同本指导文件中说明的那样应用。然而，体外诊断试剂又带来了一些独特的定义和概念，这些已在“GHTF/SG5/N6:2012: 体外诊断医疗器械临床证据-主要定义与概念”中被定义；另外，在展示临床证据和确定哪些临床证据元素适用于体外诊断器械方面也存在挑战，这些问题在“GHTF/SG5/N7:2012: 体外诊断医疗器械临床证据–科学有效性确定和性能评价”中得到解决。

What about Software as a Medical Device (SaMD)? / 独立医疗器械软件（SaMD）应如何进行临床评价？

An SaMD can best be described as software that utilizes an algorithm (logic, set of rules, or model) that operates on data input (digitized content) to produce an output that is intended for medical purposes as defined by the SaMD manufacturer. Like other medical device, SaMD clinical evaluation shall be consistent with this document. Moreover, IMDRF developed a specific guidance “Software as a Medical Device (SaMD): Clinical Evaluation SaMD WG/N41:2017” to address more detailed instructions on SaMD clinical evaluation.
SaMD 可被描述为一种软件，这种软件可利用对数据输入（数字化内容）运行的算法（逻辑、规则集或模型）生成可用于 SaMD 生产商规定的医学目的的输出。和其他医疗器械一样，本文件也适用于 SaMD 的临床评价。此外，IMDRF 编写了专门的指南“独立医疗器械软件（SaMD）：临床评价 SaMDWG/N41:2017”，为 SaMD 的临床评价提供了更加详细的说明。

6 Sources of data/documentation used in a clinical evaluation (Stage 1)/ 用于临床评价的数据 / 文件的来源（第 1 阶段）

Data relevant to the clinical evaluation may be held by the manufacturer (e.g. manufacturer sponsored pre and post market investigation reports and adverse event reports for the device in question) or in the scientific literature (e.g. published articles of clinical investigations and adverse event reports for the device in question or for comparable devices).

与临床评价有关的数据可能由生产商持有（例如生产商发起的上市前与上市后调查报告、对拟评价器械的不良事件报告），或者在科学文献中（例如已发表的对于拟评价器械或对比器械的临床试验文献以及不良事件报告）。

The manufacturer is responsible for identifying data relevant to the device and determining the types and amount of data needed for the clinical evaluation.
生产商负责识别与器械有关的数据，并决定临床评价所需要的数据类型和数量。

Where data are used from a combination of sources, the principles applicable to each source apply to that data component within the clinical evaluation.
如果所用数据来源是复合的，则适用于每一类来源的原则也应用于临床评价中的该数据部分。

6.1 Data generated through literature searching /通过文献检索产生的数据

Literature searching can be used to identify published clinical data that is not in the possession of the manufacturer that may assist the manufacturer to establish acceptable safety, clinical performance and/or effectiveness of a medical device. The data generated through literature searching may relate directly to the device in question (e.g. reports of clinical investigations of the device in question that have been performed by third parties, adverse event reports) or to comparable devices.
文献检索可用于识别并非生产商所有、却可能协助生产商证明医疗器械的可接受安全性、临床性能和／或有效性的已发表临床数据。通过文献检索产生的数据可能直接与拟评价器械（例如由第三方实施的拟评价器械临床试验报告、不良事件报告）或对比器械相关。

For some devices, clinical data generated through literature searching will represent the greater part (if not all) of the clinical evidence. Thus, when conducting a literature review reasonable efforts should be made to conduct a comprehensive search.
对于部分器械，通过文献检索产生的临床数据将构成临床证据的主要部分（即使不是全部）。因此，在进行文献综述时，必须在合理的情况下进行尽可能全面的检索。

Published data will need to be assessed with respect to its possible contribution and weighting in establishing both the performance of the device in question and its safety. Papers considered unsuitable for demonstration of performance because of poor study design or inadequate analysis may still contain data suitable for assessing the safety of the device.
已发表的数据需要对其用于证明评估器械的性能与安全性的可能贡献和权重进行评估。即使是由于不良研究设计或者不充分的分析而认为不适于证明性能的材料，也仍然可能包含适于评估器械安全性的数据。

The key elements of literature searching/ 文献检索的主要因素

The search strategy should be based on carefully constructed review questions. A protocol should be developed to identify, select and collate relevant publications to address these questions. This should be developed and executed by persons with expertise in information retrieval, having due regard to the scope of the clinical evaluation set out by the manufacturer. The involvement of information retrieval experts will help to maximise data retrieval.
检索策略应该建立在仔细地构建审核问题的基础之上。应该针对这些问题建立一个可识别、选择、对比相关出版物的方案。在有关生产商确定的临床评价的范围下，这一方案应该由具备信息检索知识的专业人员开展并实施。信息检索专家的参与将有助于优化数据检索。

The literature search protocol should include:
文献检索方案应包括：

- the sources of data that will be used and a justification for their choice;
- 所使用的数据的来源以及选择它们的理由；
- the extent of any searches of scientific literature databases (the database search strategy);
- 对所有科学文献数据库的检索范围（数据库检索策略）；
- the selection/criteria to be applied to published literature and justification for their choice; and
- 适用于出版文献的选择／标准以及选择它们的理由；以及
- strategies for addressing the potential for duplication of data across multiple publications;
- 用于解决多个发表文献中数据重复问题的策略；

Once the literature search has been executed, a report should be compiled to present the results of the search. A copy of the protocol should be included and any deviations noted. A possible format for the literature search report is located at Appendix B.
文献检索执行完毕后应编列相应的报告用于说明检索的结果。应纳入检索方案的副本并注明发生的任何偏离。附件 B 提供了文献检索报告的一种参考格式。

It is important that the literature search is documented to such a degree that the methods can be appraised critically, the results can be verified, and the search reproduced if necessary. A possible methodology is presented in Appendix C.
重要的是文献检索应该记录到此程度：其方法能够被严格评价，其结果能够验证而且如果必要的话，该检索能够得以重现。附件 C 展示了一种参考方法。

What data/documentation from the literature search should be included in the clinical evaluation? /文献检索的哪些数据／文档应该纳入临床评价?

The following documentation should be used in the clinical evaluation by the clinical evaluator:
临床评价人员应将以下文档用于临床评价：

- the literature search protocol;
- 文献检索方案；
- the literature search report; and
- 文献检索报告；以及

- published articles and other references identified as being relevant to the device in question and suitable for evaluation.
- 确定与对比器械有关并适用于评价的已发表文章以及其他参考文献。

The literature search protocol, the literature search report and copies of relevant references become part of the clinical evidence and, in turn, the technical documentation for the medical device. With respect to the clinical evaluation, it is important that the clinical evaluator be able to assess the degree to which the selected papers reflect the intended application/use of the device, etc.
文献检索方案、文献检索报告以及有关参考资文献的副本将组成临床证据的一部分，并转而成为医疗器械技术文档。关于临床评价，临床评价人员能够对所挑选文章反映该器械的预期应用／使用的程度进行评价是重要的。

Copies of the actual papers and references are necessary to allow the evaluator to review the methodology employed (potential sources of bias in the data), the reporting of results and the validity of conclusions drawn from the investigation or report. Abstracts may lack sufficient detail to allow these issues to be assessed thoroughly and independently.
提供原文与参考文献的复印件是必要的，使评价者能够审核文章中所使用的方法学（数据中潜在的偏差来源）、报告的结果以及从该研究或者报告得出的结论的有效性。摘要可能缺乏足够的细节以便对这些事项进行全面与独立的评价。

6.2 Data generated through clinical experience /通过临床经验产生的数据

These types of clinical data are generated through clinical use that is outside the conduct of clinical investigations and may relate to either the device in question or comparable devices. Such types of data may include:
此类临床数据是通过开展的临床试验以外的临床使用产生的，可能与拟评价器械或对比器械有关。此类数据可以包括：

- manufacturer-generated post market surveillance reports, registries or cohort studies (which may contain unpublished long term safety, clinical performance, and/or effectiveness data);
- 生产商产生的上市后监督报告、登记研究或者队列研究（可能包含未发表的长期安全性、临床性能和／或有效性数据）；
- adverse events databases (held by either the manufacturer or regulatory authorities);
- 不良事件数据库（由生产商或者监管机构持有）；
- data for the device in question generated from individual patients under compassionate usage programs prior to marketing of the device;
- 在器械上市之前，拟评价器械在同情使用项目中用于个体患者所产生的数据；
- details of clinically relevant field corrective actions (e.g. recalls, notifications, hazard alerts); and
- 临床相关领域纠正措施的详情（如召回、通知、危险警告等）；并且

The value of clinical experience data is that it provides real world experience obtained in larger, heterogeneous and more complex populations, with a broader (and potentially less experienced) range of end-users than is usually the case with clinical investigations[1]. The data are most useful for identifying less common but serious device-related adverse events; providing long term information about safety, clinical performance, and/or effectiveness including durability data and information about failure modes; and elucidating the end-user "learning curve". It is also a particularly useful source of clinical data for low risk devices that are based on long standing, well-characterized technology and, therefore, unlikely to be the subject of either reporting in the scientific literature or clinical investigation.
临床经验数据的价值是：通常比临床研究的病例提供了从大批、多样并且更为复杂的人群、范围更广（也许更缺乏经验）的最终用户中获得的真实经验[1]。这些数据对于识别较为少见但更为严重的器械相关不良事件尤为重要；这些数据更多地用于提供了安全性、临床性能和／或有效性的长期信息，包括耐久性数据以及失效模式信息；并阐明了最终用户的"学习曲线"。同时，它对于建立在长期稳定、特征良好技术之上、低风险器械并因而不大可能成为科学文献报告或者临床试验的对象，是一个特别有益的临床数据来源。

How may clinical experience data/documentation be used in the clinical evaluation? / 临床经验数据／文档如何用于临床评价?

If a manufacturer chooses to use clinical experience data it is important that any reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment of the information and make a conclusion about its significance with respect to the safety, clinical performance and/or effectiveness of the device in question. Reports of clinical experience that are not adequately supported by data, such as anecdotal reports or opinion, should not be used.
如果生产商选择使用临床经验数据，必须确保任何报告或者数据集中包含充足的信息，能够对信息进行合理、客观的评价，并就该信息对拟评价器械安全性、临床性能和／或有效性的意义得出结论。未得到数据支持的临床经验报告，如非正式报告或者观点不应使用。

Post market surveillance reports are compiled by the manufacturer and often include details of the device's regulatory status (countries in which the device is marketed and date of commencement of supply), regulatory actions undertaken during the reporting period (e.g. recalls, notifications), a tabulation of adverse events (particularly serious events and deaths, stratified into whether the manufacturer considers them to be device-related or not) and estimates of the incidence of adverse events. Post-marketing data about adverse events are generally more meaningful when related to usage but caution is needed because the extent of reporting may vary considerably between countries. The analyses of data within these reports may, for some devices, provide reasonable assurance of safety, clinical performance and/or effectiveness.
上市后监督报告由生产商编制，通常包括器械的管理状况的详情（器械上市的国家以及开始供应的日期）、在报告期间开展的管理活动（例如召回、通知）、不良事件表格（特别是严重事件与死亡，按照生产商是否认为与器械有关或者无关进行分级）以及不良事件发生率的估计。关于器械使用，上市后的不良事件数据通常更有意义，但由于不同国家之间对报告的范围可能有不同的考虑，因此需要对此加以注意。对于某些器械，

在这些报告中的数据分析可能为安全性、临床性能和／或有效性提供合理的保证。

It may be helpful to provide a table summarizing device-related adverse events, paying particular attention to serious adverse events, with comments on whether observed device-related adverse events are predictable on the basis of the mode of action of the device. Comment specifically on any clinical data that identifies hazards not previously considered in the risk management documentation, outlining any additional mitigation required (e.g. design modification, amendment of product literature such as inclusion of contraindications etc).
提供汇总的与器械相关的不良事件的表格可能是有帮助的。应对严重不良事件予以特别关注，在基于器械的工作模式上，评论所观察到的与器械相关的不良事件是否可以预见。应对识别了在以前风险管理文件中未考虑的危险的临床数据进行特别评价，并概述所要求的其他降低风险措施（如设计改正、修改产品资料如纳入新的禁忌症等）。

Registries that fit the IMDRF definition and qualifiers have potential to be used for regulatory decision making (IMDRF/REGISTRY WG/N33 FINAL: 2016 - *Principles of International System of Registries Linked to Other Data Sources and Tools*). To support regulatory purposes, the quality and robustness of registry data used must be carefully assessed. Guidance has been provided on methodological principles in the clinical evaluation across the device lifecycle using international registries (IMDRF/Registry WG/N42FINAL:2017 - *Methodological Principles in the Use of International Medical Device Registry Data*), and the use of registry-generated data in support of regulatory decisions (IMDRF/Registry WG/N46 FINAL: 2018 - *Tools for Assessing the Usability of Registries in Support of Regulatory Decision-Making*).
符合 IMDRF 定义及限定语内容的登记系统有可能用于监管决策的制定（IMDRF/REGISTRYWG/N33 FINAL: 2016-*国际登记系统与其他数据源和工具相关联的原则*）。为了支持监管目的，必须对所用登记数据的质量和可靠性进行谨慎的评估。已有指导原则提供了关于在器械生命周期内利用国际登记系统开展临床评价的方法原则（IMDRF/RegistryWG/N42FINAL: 2017-*用国际医疗器械登记数据的方法原则*）以及如何使用登记系统产生的数据来支持监管决策（IMDRF/RegistryWG/N46FINAL: 2018-*登记系统用于支持监管决策的可用性评估工具*）。

[1] In contrast, clinical investigations involve the use of specific inclusion criteria to create a homogenous population to reduce sources of variation and, therefore, increase confidence that the outcomes observed in the investigation are due to intervention with the device in question. Also, investigators participating in the investigation are chosen on the basis of their expertise and competence and often undergo training over and above that available to other end-users of the device.

[1] 与此相反，临床试验涉及到使用特定的纳入准则来创建同质的人群，以减少来源的变化。这样就增加了置信度，认为研究中所观察的结局是由于拟评价器械的干预造成的。同样，参与试验的研究人员是基于其专业知识和能力而选择的，通常接受的器械培训要超过其他终端用户。

6.3 Data from clinical investigations/通过临床试验产生的数据

The guidance included within this section applies to clinical investigations carried out by or on behalf of a manufacturer specifically for the purposes of conformity assessment in accordance with applicable regulations. Such clinical investigations are generally expected to be designed, conducted and reported in accordance with ISO 14155:2011, *Clinical investigation of medical devices for human subjects -- Good clinical practice*, or to a comparable standard, and in compliance with local regulations.
本章中包括的指导原则适用于生产商或代表生产商根据适用的规定，出于符合性评估的目的而专门开展的临床试验。通常情况下，应该根据 ISO14155:2011《*适用于人类受试者的医疗器械临床试验—临床试验质量管理规范*》的规定或者等效标准，并在符合当地法规的情况下，对临床试验进行设计、实施和报告。

It is recognised that where manufacturers source clinical investigation data reported in the scientific literature (i.e. investigations of either the device in question or comparable devices that are undertaken by a third party), the documentation readily available to the manufacturer for inclusion in the clinical evaluation is likely to be no more than the published paper itself.
已达成共识的是：如果生产商提供在科学文献中报告的临床试验数据（如由第三方开展的拟评价器械或者对比器械的试验），那么提供给生产商准备纳入临床评价的文档可能仅仅是发表文献本身。

What clinical investigation documentation/data should be used in the clinical evaluation?
哪些临床试验文档／数据应该用于临床评价?

Where a clinical investigation has been carried out by or on behalf of a manufacturer, it is expected that documentation relating to the design, ethical and regulatory approvals, conduct, results and conclusions of the investigation needed for the clinical evaluation will be available for consideration, as appropriate. These may include:
在由生产商或代表生产商开展临床试验的情况下，在适用情况下应该提供临床评价所需要的有关设计、伦理和监管批准、实施、结果以及结论的全部文档以供考虑。这些可能包括：

- the clinical investigation plan;
- 临床试验方案；
- clinical investigation plan amendments and the rationale for these changes;
- 临床试验方案的修改以及修改的理由；
- the relevant Ethics Committee documentation, opinion(s) and comments for each investigation site, including a copy of the approved informed consent form(s) and patient information documents;
- 有关伦理委员会的文档、意见以及对每一试验中心的评价，包括经过批准的知情同意书以及患者须知文件的复印件；
- case report forms, monitoring and audit records;
- 病例报告表、监视及审查记录；

- Regulatory Authority approvals and associated correspondence as required by applicable regulations;
- 适用的法规要求的监管机构批准及其相关的往来函件；
- Documents related to financial disclosure, financial agreements or conflict of interests; and
- 与财务披露、财务协议或利益冲突等相关的文件；以及
- the signed and dated final report.
- 经签署并注明日期的总结报告。

The clinical investigation plan sets out how the study was intended to be conducted. It contains important information about the study design such as the selection and assignment of participants to treatment, masking (blinding of participants and investigators) and measurement of responses to treatment, which may be important sources of bias that can be assessed and discounted when trying to determine the actual performance of the device. In addition the clinical investigation plan sets out the intended participant follow-up, approaches to statistical analyses and methods for recording outcomes, which may impact on the quality, completeness and significance of results obtained for performance and safety outcomes.
临床试验方案计划了如何开展研究。方案包含关于研究设计的重要信息，如受试者的选择与分配、设盲（参与人员与研究者的设盲）以及治疗反馈的评价方法。在决定器械的实际性能时，这些信息很可能属于重要的偏倚来源并进行评价和处理。同时，临床试验方案还规定了对受试者的随访、统计分析方法以及结果的记录方法，这些因素都可能影响到性能与安全性结果的质量、完整性以及意义。

Also, by having the clinical investigation plan, its amendments and the final report available, the evaluator will be able to assess the extent to which the investigation was conducted as planned and, where deviations of from the original plan have occurred, the impact those deviations had on the veracity of the data generated and the inferences that can be drawn about the safety, clinical performance and/or effectiveness of the device from the investigation.
另外，通过提供临床试验方案、其修正案以及总结报告，评价人员将能够评估以下情况：试验按计划实施的程度；如果出现原始方案偏离，该偏离对产生数据精确性的影响；以及从试验中得出的关于器械安全性、临床性能和／或有效性的推断。

The final report should be signed by its author and appropriate reviewers to provide assurance that the final report is an accurate reflection of the conduct and results of the clinical investigation.
总结报告应由作者以及适当的审评员签字，以保证该总结报告是临床试验活动和结果的准确反映。

Another important consideration of the evaluation will be to assess whether the conduct of the investigation was in accordance with the current applicable ethical standards that have their origin in the Declaration of Helsinki and in accordance with applicable regulations. Clinical investigations not in compliance with applicable ethical standards or regulations should be rejected. The reasons for rejection of the investigation should be noted in the report.
评价的另一个重要考虑因素是评估试验活动是否符合目前适用的、源于《赫尔辛基宣

言》的伦理准则以及是否符合所适用的法规。不符合适用的伦理准则或法规的临床试验应被拒绝。拒绝试验的理由应在报告中予以说明。

7 Appraisal of clinical data (Stage 2)/ 临床数据评估（第 2 阶段）

The purpose of undertaking appraisal of the data is to understand the merits and limitations of the clinical data. Each piece of data is appraised to determine its suitability to address questions about the device, and its contribution to demonstrating the safety, clinical performance and/or effectiveness of the device (including any specific claims about safety, clinical performance and/or effectiveness).
开展数据评估的目的是了解临床数据的优点和局限性。对每一个数据进行评估，确定其对器械所关注问题的适宜性以及其对证明器械安全性、临床性能和／或有效性的贡献（包括关于安全性、临床性能和／或有效性的任何特定的宣称）。

What should the appraisal cover?/ 评估包括什么内容?

The data needs to be suitable for appraisal. It should be assessed for its quality and for its relevance to the device in question (i.e. the data must be either generated for the device in question or for a comparable device) and its intended use. In addition, any reports or collations of data should contain sufficient information for the evaluator to be able to undertake a rational and objective assessment of the information and make a conclusion about its significance with respect to the safety, clinical performance and/or effectiveness of the device in question.
数据应适合评估。应对数据的质量以及与拟评价器械和预期用途的相关性（即数据必须由拟评价器械或者对比器械产生）进行评估。另外，任何报告或者数据集应包含足够的信息，以允许评价人员对信息进行合理、客观的评估，并对其在证明拟评价器械的安全性、临床性能和／或有效性方面的贡献得出结论。

Further appraisal needs to be undertaken to determine the contribution of each data subset to establishing the safety, clinical performance and/or effectiveness of the device. The evaluator should examine the methods used to generate/collect the data and assess the extent to which the observed effect (performance or safety outcome(s)) can be considered to be due to intervention with the device or due to confounding influences (e.g. natural course of the underlying medical condition, concomitant treatment(s)) or bias[2]. The evaluator should also assess whether clinical data are collected ethically and in conformance with good clinical practice (such as ISO 14155:2011), and whether clinical data are applicable to the population for which the marketing authorization is being sought. Refer to Appendix D for details regarding considerations of data from various jurisdictions.
为了确定每个数据子集在证明器械安全性、临床性能和／或有效性方面的贡献，还需要开展进一步的评估。评价人员应该检查产生／收集数据的方法，并评估所观察到的效果（性能或安全性结果）的程度是否可以视为是由于器械干预的原因、或者是由于混杂的影响（比如医疗症状的自然进展、伴随治疗）、或者是由于偏倚[2]引起的。评价人员还应当评估临床数据的收集是否符合伦理、是否遵守临床试验质量管理规范（如

ISO14155:2011）以及临床数据是否适用于上市批准后所面向的人群。附件 D 提供了可参考的评价来源于不同司法管辖区数据的考虑因素。

There is no single, well established method for appraising clinical data. Therefore, the evaluator should identify, in advance, the appropriate criteria to be applied for a specific circumstance.
不存在单一、完全成熟的评估临床数据的方法。因此，评价人员应该事先在特定情况下识别所采用的适当标准。

These criteria should be applied consistently. Some examples to assist with the formulation of criteria are given in Appendix E.
这些标准应连贯采用。帮助建立标准的示例在附件 E 中给出。

For many lower risk devices and devices based on long standing technology, the available data may be qualitative rather than quantitative in nature, so the evaluation criteria should be adjusted accordingly. The criteria adopted for the appraisal should be justified by the evaluator.
对于很多低风险器械以及建立在长期成熟技术基础上的器械，所提供的数据可能是定性数据而非定量数据，因此评估标准也应相应调整。评估采用的标准应由评价人员说明理由。

Although there will be some overlap of safety, clinical performance and/or effectiveness data, the data should be categorized to allow for separate analysis. Additional categories may also be needed, depending on the nature and intended use of the device to address additional claims. The data should also be weighted according to its relative contribution. An example of a method of data appraisal is shown in Appendix F.
尽管存在安全性、临床性能和／或有效性数据的重迭，还是应该对数据进行分类，以允许进行单独的分析。根据具有额外声明的器械的性质以及其预期用途，很可能会需要额外的分类。同时，还应该根据数据的相对贡献，对其进行加权。对数据进行评估的示例方法参见附件 F。

8 Analysis of the clinical data (Stage 3)/ 临床数据分析（第 3 阶段）

The goal of the analysis stage is to make a benefit/risk determination if the appraised data sets available for a medical device collectively demonstrate the safety, clinical performance and/or effectiveness of the device in relation to its intended use.
分析阶段的目标是：通过受益／风险分析确定可用于医疗器械的评估数据集，是否能够在总体上证明器械用于预期用途的安全性、临床性能和／或有效性。

The methods available for analysis of clinical data generally are either quantitative or qualitative. Given the context within which most medical devices are developed (i.e. limited need for clinical investigations because of incremental changes in device design and therefore high use of literature and experience data), it is most likely that qualitative (i.e. descriptive) methods will

need to be used.
临床数据分析的方法通常不是定量就是定性。鉴于大部分医疗器械的发展过程已经成熟（比如由于器械设计上的渐进变化以及大量使用文献和实践数据，临床试验的需求很有限），则很可能只需要使用定性的方法（如描述性方法）。

Any evaluation criteria developed and assigned during the appraisal stage can be used to identify those sets of data which may be considered to be "pivotal" to the demonstration of the safety, clinical performance and/or effectiveness of the device, respectively. It may be useful to explore the results of the pivotal datasets, looking for consistency of results across particular device performance characteristics and identified risks. If the different datasets report similar outcomes, certainty about the performance increases. If different results are observed across the datasets, it will be helpful to determine the reason for such differences. Regardless, all data sets should be included.
在评估阶段开发和制定的评价标准可用于分别地识别对证明器械安全性、临床性能和 / 或有效性最为"关键"的数据集。探索关键数据集的结果，寻找特定器械性能特征与风险识别结果之间的一致性可能很有作用。如果不同的数据集报告了相似的结果，性能的确定性就增加。如果数据中观察到不同的结果，确定造成不同结果的原因将很有意义。不管结果如何，所有数据集均应包括在内。

As a final step the evaluator should consider the basis on which it can be demonstrated that the combined data confirm:
作为最后一个步骤，评价人员应考虑，这些组合数据能够证实：

- the device performs as intended by the manufacturer;
- 器械达到生产商的预期的性能；
- the device does not pose any undue safety concerns to either the recipient or end-user; and
- 器械未对使用者或者最终用户产生任何不适当的安全性问题；以及
- any risks associated with the use of the device are acceptable when weighed against the benefits to the patient.
- 任何与器械使用有关的风险，在与患者的利益相比较时，都在可接受的范围之内。
- compliance with the relevant Essential Principles;
- 符合相关的基本原则；
- whether post market clinical follow up or post approval study is necessary.
- 是否有必要开展上市后临床跟踪随访或批准后研究。

Such considerations should take into account the number of patients exposed to the device, the type and adequacy of patient monitoring, the number and severity of adverse events, the adequacy of the estimation of associated risk for each identified hazard, the severity and natural history of the condition being diagnosed or treated. The availability of alternative diagnostic modalities or treatments and current standard of care should also be taken into consideration.
这些因素应该予以考虑：暴露于该器械下的患者数量、患者监视的类型和适当性、不良事件的数量以及严重性、对每一识别危害的相关风险估计的充分性、诊断与治疗病症的严重性以及自然史。还应考虑替代诊断方式或治疗的可用性以及当前的诊疗标准。

The product literature and instructions for use should be reviewed to ensure they are consistent with the data and that all the hazards and other clinically relevant information have been identified appropriately.

应该对产品资料与使用说明进行审核，以保证它们与数据一致，并且所有危害以及其他相关临床信息都已经适当的识别。

9 The Clinical Evaluation Report/ 临床评价报告

At the completion of the clinical evaluation process a report should be compiled that outlines the scope and context of the evaluation; the inputs (clinical data); the appraisal and analysis stages; and conclusions about the safety, clinical performance and/or effectiveness of the device in question.

临床评价程序结束后，应编制报告，概述评价的范围和内容；输入（临床数据）；评估和分析过程；对评估器械安全性，临床性能和/或有效性作出结论。

The clinical evaluation report should contain sufficient information to be read as a stand alone document by an independent party (e.g. regulatory authority or notified body). It is important that the report outline:

临床评价报告应包含足够的信息，并可以作为单独文件由独立方阅读（如管理部门或公告机构）。报告对以下情况进行概述至关重要：

- the technology on which the medical device is based, the intended use of the device and any claims made about the device's safety, clinical performance and/or effectiveness ;
- 该医疗器械基于的技术、器械的预期用途以及任何对器械安全性，临床性能和/或有效性的宣称；
- the nature and extent of the clinical data that has been evaluated; and
- 所评价的临床数据的性质和程度；以及
- how the referenced information (recognised standards and/or clinical data) demonstrate the safety, clinical performance and/or effectiveness of the device in question.
- 引用信息（公认标准以及/或者临床数据）如何证明该评估器械的安全性，临床性能和/或有效性。

The clinical evaluation report should be signed and dated by the evaluator(s) and accompanied by the manufacturer's justification of the choice of evaluator.

临床评价报告应由评价人签名、注明日期并附上生产商选择评价人的理由。

A suggested format for the clinical evaluation report is located at Appendix G. Again, it should be noted that the level of detail in the report content can vary according to the scope of the clinical evaluation. For example, where a manufacturer relies on clinical data for a comparable device which has been the subject of an earlier clinical evaluation (for which the manufacturer holds the evaluation report), it may be possible to cross-reference the data summary and analysis sections to the earlier clinical evaluation report, which also becomes part of the clinical evidence

for the device in question.

临床评价报告的一种推荐格式参见附件 G。同时应注意，报告内容的详细程度可视临床评价的范围而有所不同。例如，如果生产商依赖的是对比器械的临床数据，而该器械又属于先前临床评价的对象（生产商持有该器械的评价报告），很可能会交叉引用先前临床评价报告的数据摘要与分析章节，同时该报告也将成为拟评价器械临床证据的一部分。

[2] Bias is a systematic deviation of an outcome measure from its true value, leading to either an overestimation or underestimation of a treatment's effect. It can originate from, for example, the way patients are allocated to treatment, the way treatment outcomes are measured and interpreted, and the recording and reporting of data

[2] 偏倚是对结果指标从其真实值的系统性偏离，会导致对治疗效果的高估或者低估。偏倚可能源于分配患者治疗的方式、治疗结果测量、阐述以及数据记录和报告的方式。

Appendices
附件

Appendix A: Some Considerations for Comparability
附件 A:可比性的考虑事项

The examples given below are potential aspects for consideration with respect to comparability. There should still be summary documentation provided describing how these elements support comparability. Further, there may be cases where additional testing is needed to establish a particular degree of comparability.
以下示例为在考虑可比性时需要注意的一些方面。同时还应当提供总结性文档来论述这些因素内容如何能够对可比性形成支持。并且，在有些情况下可能需要开展额外的测试以确立特定的可比性的程度。

Intended use: / 预期用途：

- indications for use, including the disease or condition the device will diagnose, treat, prevent, cure or mitigate
  适应症，包括器械将用于诊断、治疗、预防、治愈或缓解的疾病或状况
- the severity and stage of disease
  疾病的严重程度和阶段
- patient population (age, gender, anatomy, physiology, other aspects)
  患者人群（年龄、性别、解剖结构、生理学信息、其他方面）
- the site of application to/in the body (organs, parts of the body, tissues or body fluids contacted by the device)
  使用部位（器官、身体部分、器械所接触的组织或体液）
- type of contact (contact with mucosal membranes/ invasiveness/ implantation)
  接触类型（黏膜接触 / 侵入 / 植入）
- duration of use or contact with the body
  持续使用时间或与人体接触的时间
- environment of use (e.g. healthcare facility, home)
  使用环境（如医疗机构、家中）
- intended user (use by health care professional / lay person)
  预期使用者（由专业医务人员 / 非专业人士使用）
- repeat applications, including any restrictions as to the number or duration of reapplications
  重复使用，包括重复使用次数或持续时间的任何限制
- other aspects
  其他方面

Technical: / 技术：

- design (e.g. dimensions and design tolerances; how the different components of the device system work together)
  设计（如尺寸和设计公差；器械系统上的不同组件如何相互配合发挥作用）
- material (e.g. chemical formulation, additives, processing such as forged, state such as crystalline)
  材料（如化学配方、添加剂、加工方法（如铸造）、状态（如结晶状态）等）

- specifications and properties (e.g. physicochemical properties such as type and intensity of energy, wavelength, porosity, particle size, viscosity, nanotechnology, specific mass, atomic inclusions such as nitrocarburising, oxidability, tensile strength anddegradation characteristics)
  规格和特性（例如，理化特性诸如能量强度和能量类型、波长、孔隙率、粒度、黏度、纳米技术、比质量、原子结构诸如氮碳共渗、氧化性、抗张强度和降解特征等）
- deployment methods (if relevant)
  释放方法（如果相关）
- critical performance requirements
  关键性能要求
- principles of operation
  工作原理
- other aspects
  其他方面

Biological: / 生物学：

- biocompatibility of materials in contact with body fluids/tissues
  与体液／组织接触的材料的生物相容性
- biological action (if applicable)
  生物作用（如适用）
- degradation mechanism and profile (if applicable)
  降解机制及概况（如果适用）
- biological response (e.g., inflammatory response, immune response, tissue integration)
  生物学反应（例如：炎性反应，免疫反应，组织融合）
- other aspects
  其它方面

Appendix B: A Possible Format for the Literature Search Report

附件 B：文献检索报告的一种参考格式

1. Device name/model
器械名称 / 型号

2. Scope of the literature search[should be consistent with scope of clinical evaluation]
文献检索的范围[应与临床评价的范围相符]

Methods /方法

(i) Date of search
检索日期

(ii) Name of person(s) undertaking the literature search
文献检索人员姓名

(iii) Period covered by search
检索时间范围

(iv) Literature sources used to identify data
确定数据的文献来源

- scientific databases – bibliographic (e.g.MEDLINE,EMBASE),specialized databases(e.g.MEDION)
  科学数据库–书目类（如 MEDLINE、EMBASE），专业数据库（如 MEDION）
- systematic review databases (e.g. Cochrane Collaboration)
  系统性综述数据库（如 Cochrane Collaboration）
- clinical trial registers (e.g. CENTRAL),
  临床试验注册中心（如 CENTRAL），
- adverse event report databases(e.g.MAUDE,IRIS)
  不良事件报告数据库（如 MAUDE、 IRIS）
- reference texts
  参考文本

[Include justification for choice of sources and describe any supplemental strategies (e.g. checking bibliography of articles retrieved, hand searching of literature) used to enhance the sensitivity of the search]
[包括对来源选择的理由，并说明用于改善查询敏感性的辅助性的策略(如检查检索文章的书目、人工查询文献等)]

(v) Database search details
数据库检索详细情况

- search terms(key words, indexing headings) and their relationships(Boolean logic)
  检索词（关键词、索引词）及其关系（布尔逻辑）
- medium used (e.g. online, CD-ROM(incl publication date and

edition))[Attach copy of downloaded, unedited search strategy]
所用媒体（如线上媒体、CD-ROM（包括发布日期和版本））[随附下载副本、未经编辑的检索策略副本]

(vi) Selection criteria used to choose articles
用于选择文章的选择标准

Outputs / 结果

(i) Attach copy of literature citations retrieved from each database search
随附在每个数据库中检索到的文献引文的副本

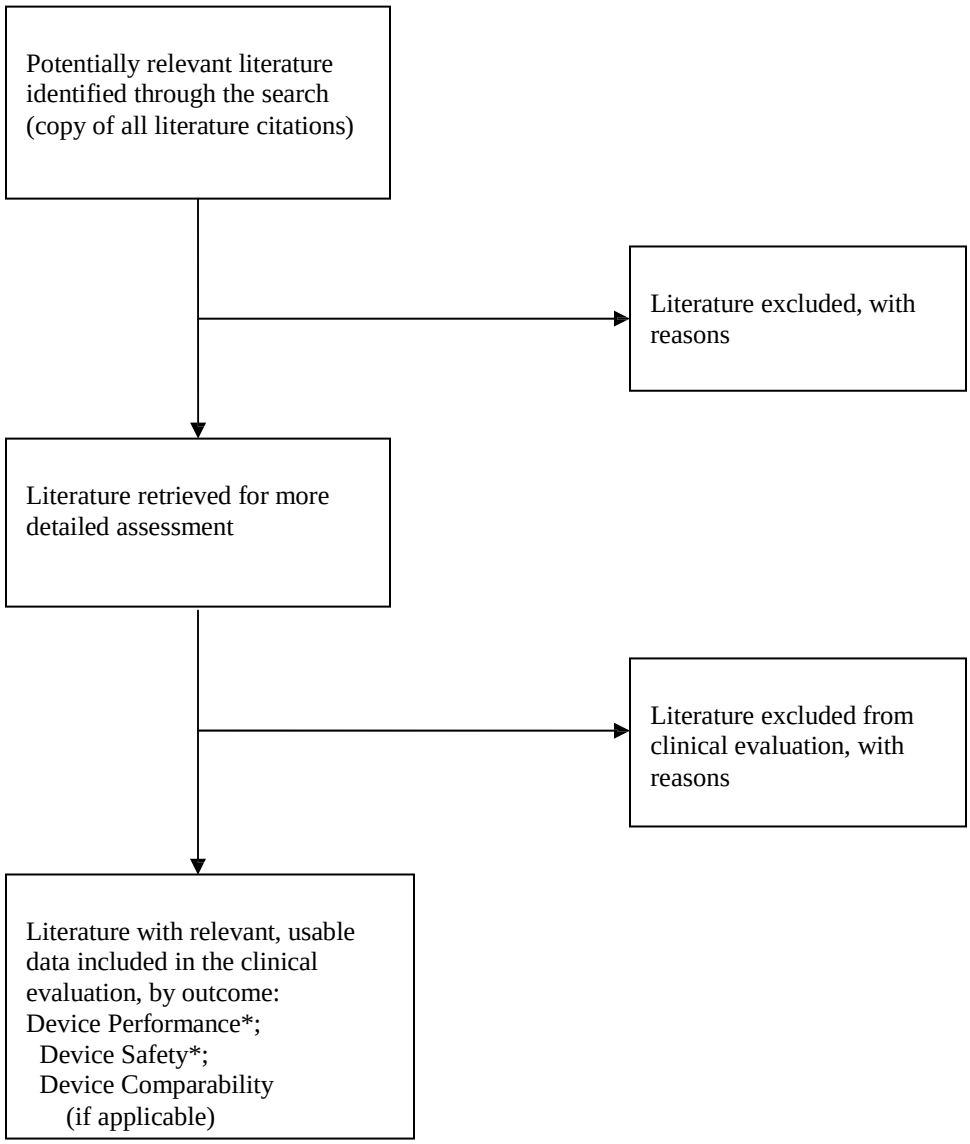
(ii) Data selection process
数据选择程序
[Attach flow chart and associated tables showing how all citations were assessed for suitability for inclusion in the clinical evaluation (see Appendix B)]
随附流程表及有关表格，说明如何对所有引用是否适于纳入临床评价进行验证（参见附件 B）

Notes: / 备注：

EMBASE	Excerpta Medica published by Elsevier Elsevier 出版的《医学文摘》
CENTRAL	The Cochrane Central Register of Controlled Trials Cochrane 协作网对照临床试验注册中心
IRIS	The TGA's medical device Incident Report Investigation Scheme TGA 医疗器械不良事件报告研究计划
MAUDE	US FDA's Manufacturer And User Facility Device Experience database 美国食品药品管理局医疗器械生产商和使用者报告系统
MEDION	Database that indexes literature on diagnostic tests 对诊断试验文献进行检索的数据库
MEDLINE	Published by US National Library of Medicine 由美国国家医学图书馆出版

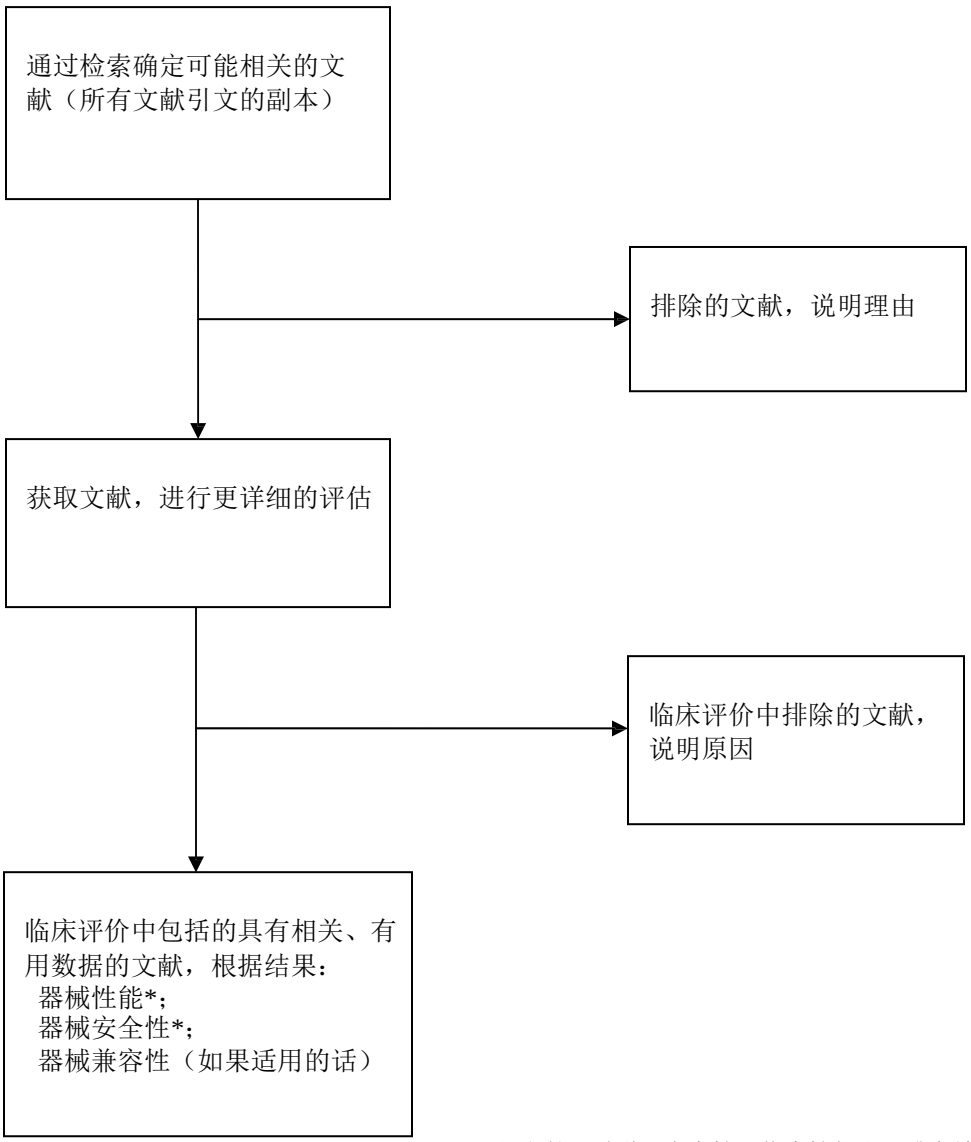
Appendix C: A possible methodology for documenting the screening and selection of literature within a literature search report[3]

附件 C：文献检索报告中文献筛选与选择的可能记录方法 [3]



* some literature will address issue of safety, clinical performance and/or effectiveness

[3] Adapted from Moher, D., Cook, D. J., Eastwood, S., Olkin, I., Rennie, D., & Stroup, D. F. Improving the quality of reports of meta-analyses of randomised controlled trials: the QUORUM statement. Quality of Reporting of Meta-analyses. *Lancet* 1999; 354: 1896-1900.



*一些文献同时说明安全性、临床性能和 / 或有效性的问题

[3] 引自 Moher,D.,Cook,D.J.,Eastwood,S.,Olkin,I.,Rennie,D.,&Stroup,D.F.提高随机对照试验中汇总分析报告的质量：QUOROM 报告.汇总分析报告的质量 Lancet1999；354: 1896-1900.

Appendix D: Considerations for the Application of Clinical Investigation Data Generated from Different Jurisdiction(s)
附件 D：采用不同司法管辖区域的临床研究数据时的考虑事项

When clinical investigations are conducted ethically in accordance with applicable good clinical practice, the clinical data should be accepted for consideration in any jurisdiction. However, the applicability of the clinical data may be dependent on differences in regulatory requirements, intrinsic and extrinsic factors.
根据适用的临床试验质量管理规范在符合伦理标准的情况下开展临床试验时，所产生的临床数据应被任何司法管辖区域所接受予以考虑。但临床数据的适用性取决于监管要求、内在和外在因素的差异性。

1. Considerations for differences in regulatory requirements
1.不同法规要求的考虑

The clinical investigation should be conducted in compliance with both regulations required in the jurisdictions where the investigation is performed as well as where the investigational device is going to be reviewed for the market approval. Aspects of the investigation that do not meet the requirements for study conduct in each jurisdiction should be explained and justified.

开展临床试验时应当同时遵守试验开展所在司法管辖区域以及试验器械申报所在司法管辖区域的法规。试验中如果存在未能满足司法管辖区域相关研究要求的部分，则该部分内容应当予以解释和论证。

2. Considerations for intrinsic and extrinsic factors
2.内在及外在因素的考虑

The intrinsic and extrinsic factors related to applicability may include:

与可用性相关的内在和外在因素包括：

1) Intrinsic factors: human genetic characteristics or demographic factors, such as race, age, gender, *etc.*;

1）内在因素：人类遗传学特征或人口学特征的影响因素，包括人种、年龄、性别等方面；

2) Extrinsic factors: clinical practice, social environment, natural environment, cultural factors, life behavioral factors, rare or regional diseases, *etc*.

2）外在因素：临床实践、社会环境、自然环境、文化因素、生活行为因素、罕见病或地

方性共病等。

The clinical practice may include method for utilization by users, clinical facilities, levels of clinical skill, standards of care, criteria of diagnosis and concepts of treatment, *etc*. For instance, differences in clinical facilities and levels of clinical skill can affect the extrapolation of the data to intended clinical practice and the differences can impact the safety, clinical performance, and/or effectiveness of the devices which require complex operation skills. Different standards of care can affect the analysis of the benefits and risks of the studied device relative to standard practice. In addition, different diagnosis criteria and treatment concepts can also impact the compliance with relevant local guidelines for clinical practice.

临床操作方面可能包括用户使用的方法、临床设施、临床技术水平、医疗护理标准、诊断标准和治疗理念等。例如，临床设施和临床技术水平上的差异可以影响预期临床操作结果的数据外推，而且对于操作技术性要求较高的器械而言，这种差异还会影响到其安全性、临床性能和／或有效性。不同的医疗护理标准可以影响试验用器械相对于标准操作规范的风险／受益分析结论。此外，不同的诊断标准和治疗理念也会影响到产品对当地临床操作指南的符合性。

The above considerations should be justified according to specific circumstances such as development status, the use experience in clinical practice, and the understanding on related diseases and their diagnosis and treatment methods. Where it is determined that some factors could have significant influence on the clinical investigation data, appropriate methods should be adopted to reduce or eliminate the influences. In those cases, additional clinical investigation may be required. Where it is determined that some factors have no significant influence, a brief explanation may be required.

上述考虑因素应当根据具体情况进行论证，例如器械发展现状、临床操作经验、对于相关疾病及其诊疗方法的认知等。如果确定了部分因素会对临床试验数据产生显著影响，则应采取适当的方法来降低或者消除这种影响。那些情况下有可能需要开展额外的临床试验。如果确定部分因素并不会造成显著影响，则可能要求提供简要的解释说明。

Appendix E: Some Examples to Assist with the Formulation of Criteria
附件 E：帮助建立标准的部分示例

The following are examples of questions to ask to assist with the formulation of criteria for data appraisal for different type of data sets. These examples are not meant to be comprehensive with regards to study types or all potential questions.
以下问题示例旨在帮助确立不同类型数据的数据评估标准。但这些示例并未完全涵盖所有的研究类型或者全部潜在的问题。

Randomised controlled trial	Clinical investigation where subjects are randomized to receive either a test or reference device or intervention and outcomes and event rates are compared for the treatment groups.
随机对照试验	即受试者随机接受一种试验器械或对照器械或干预，并比较各治疗组之间的结果和事件发生率的临床研究

- Were the inclusion and exclusion criteria specified?
  是否指定入选及排除标准？
- Was the assignment to the treatment groups really random?
  治疗组的分配是否真正随机？
- Was the treatment allocation concealed from those responsible for recruiting subjects?
  是否对负责招募受试者的人员隐蔽了治疗分配？
- Was there sufficient description about the distribution of prognostic factors for the treatment groups?
  是否对治疗组预后因素的分布有足够的说明？
- Were the groups comparable at baseline for these factors?
  对于这些因素，各组在基线时是否具有可比性？
- Were outcome assessors blinded to the treatment allocation?
  治疗分配是否对结果评估者设盲？
- Were the care providers blinded?
  提供护理的人员是否设盲？
- Were the subjects blinded?
  受试者是否设盲？
- Were all randomized participants included in the analysis?
  是否全部随机分配的受试者都包括在分析之中？
- Was a point estimate and measure of variability reported for the primary outcome?
  是否对主要结果报告了点估计和变异性指标？

Cohort study	Data are obtained from groups who have and have not been exposed to the device (e.g. historical control) and outcomes compared
队列研究	即从暴露或者未暴露于器械下（如历史对照）的组中获取数据并对结果进行对比。

- Were subjects selected prospectively or retrospectively?
  受试者的选择是前瞻性的还是回顾性的？
- Was an explicit description of the intervention provided?
  是否对提供的干预进行了清楚的说明？
- Was there sufficient description about how the subjects were selected for the new intervention and comparison groups?
  是否对如何选择受试者进行新的干预以及对照组进行了足够的说明？
- Was there sufficient description about the distribution of prognostic factors for the new intervention and comparison groups?
  是否对新干预以及对照组的预后因素分布进行了足够说明？
- Were the groups comparable for these factors?
  对于这些因素，各组是否具有可比性？
- Did the study adequately control for potential confounding factors in the design or analysis?
  研究是否对设计或者分析中的潜在混淆因素进行了充分的控制？
- Was the measurement of outcomes unbiased (i.e. blinded to treatment group and comparable across groups)?
  结果指标是否无偏倚（即是否对治疗组和对照组设盲）？
- Was follow-up long enough for outcomes to occur?
  随访期限是否足以产生结果？
- What proportion of the cohort was followed up and were there exclusions from the analysis?
  随访的队列比例是多少，是否有数据从分析中排除？
- Were drop-out rates and reasons for drop-out similar across intervention and unexposed groups?
  接受干预和未接受干预组之间的退出率和退出原因是否相似？

Case–control study Patients with a defined outcome and controls without the outcome are selected and information is obtained about whether the subjects were exposed to the device

病例对照研究 选择发生规定结果的患者和没有发生该结果的对照患者，并获取受试者是否暴露于器械的信息

- Was there sufficient description about how subjects were defined and selected for the case and control groups?
  是否对如何定义以及选择病例和对照组的受试者进行了足够的说明？
- Was the disease state of the cases reliably assessed and validated?
  病例的病症是否经过可靠评估与确认？
- Were the controls randomly selected from the source of population of the cases?
  对照组是否从病例人群中随机选择？
- Was there sufficient description about the distribution of prognostic factors for the case and control groups?
  是否对病例以及对照组预后因素的分布进行了足够说明？
- Were the groups comparable for these factors?
  对于这些因素，各组是否具有可比性？

- Did the study adequately control for potential confounding factors in the design or analysis?
  研究是否对设计或者分析中的潜在混淆因素进行了充分的控制？
- Was the new intervention and other exposures assessed in the same way for cases and controls and kept blinded to case/control status?
  是否以相同方式评估了病例和对照组的新干预与其他暴露因素并且对病例／对照情况保持设盲？
- How was the response rate defined?
  应答率是如何定义的？
- Were the non-response rates and reasons for non-response the same in both groups?
  两个组中的无应答率以及无应答的原因是否相同？
- Was an appropriate statistical analysis used?
  是否使用了适当的统计分析？
- If matching was used, is it possible that cases and controls were matched on factors related to the intervention that would compromise the analysis due to over-matching?
  如果使用了匹配，是否有可能由于病例与对照组在有关干预的因素方面匹配过度而影响分析？

Case series The device has been used in a series of patients and the results reported, with no control group for comparison

病例系列 器械已用于一系列病例并报告了结果，不设立对照组进行比较

- Was the series based on a representative sample selected from a relevant population?
  病例系列是否基于从相关人群中选择的代表性样本？
- Were the criteria for inclusion and exclusion explicit?
  入选及排除标准是否明确？
- Did all subjects enter the survey at a similar point in their disease progression?
  是否全部进入调查的受试者均处于相似的疾病病程？
- Was follow-up long enough for important events to occur?
  随访期限是否足以产生重要事件？
- Were the techniques used adequately described?
  是否对使用的技术进行了充分说明？
- Were outcomes assessed using objective criteria or was blinding used?
  结果是使用客观标准评估还是盲蔽使用？
- Did all subjects enter the survey at a similar point in their disease progression?
  如果进行子系列的比较，是否对该系列以及预后因素的分布进行了充分的说明？

Adapted from: Guidelines for the assessment of diagnostic technologies. Medical Services Advisory Committee 2005

引自：诊断技术评估指导原则。医疗服务咨询委员会 2005

Appendix F: A Possible Method of Appraisal
附件 F：一种可能的评估方法

There are many methods that can be used to appraise and weight clinical data. An example of possible appraisal criteria is given in Tables F1 and F2. The criteria may be worked through in sequence and a weighting assigned for each dataset. The data suitability criteria can be considered generic to all medical devices (Table F1), however the actual method used will vary according to the device considered.
有很多方法可用于评估并衡量临床数据。在表格 F1、F2 中给出了可能使用的评估标准。该标准通过序列和分配给每一个数据集的权重实施。虽然数据的适宜性标准对所有医疗器械是通用（表格 F1）的，但由于拟评价器械不同，实际使用的方法可能各有不同。

To assess the data contribution criteria of the suitable data, the evaluator should sort the data sets according to source type and then systematically consider those aspects that are most likely to impact on the interpretation of the results (Table F2). There is scope for the evaluator to determine what types of issues are most important in relation to the nature, history and intended clinical application of the device. The criteria used in the example below are based around the sorts of issues that could be considered for devices of higher risk, such as characteristics of the sample, methods of assessing the outcomes, the completeness and duration of follow-up, as well as the statistical and clinical significance of any results.
为评估适宜数据的数据贡献标准，评估人员应该根据来源类型对数据集进行分类，然后对最有可能影响结果阐述的因素进行系统地考虑（表格 F2）。评价人员应该有一个范围来确定哪一类问题对器械性质、历史以及预期临床应用最为重要。以下示例中使用的标准是基于具有较高风险的器械所关注的各种问题，诸如样品的特征、评估结果的方法、随访的完成度和期限、以及结果的统计和临床意义等。

In this example, the weightings would be used to assess the strength of the datasets' contribution to demonstrating overall safety, clinical performance and/or effectiveness of the device (Stage 3, see section 8). As a general guide in using this example, the more level 1 grades, the greater the weight of evidence provided by that particular dataset in comparison to other datasets, however, it is not intended that the relative weightings from each category be added into a total score.
在这一示例中，使用权重方法来评估数据集对证明器械总体安全性、临床性能和 / 或有效性贡献的强度（第 3 阶段，见第 8 章）。作为使用这一示例的通用指导，分级水平 1 越多，与其他数据集相比，该数据集提供的依据权重就越大。但并非每一类型的相对权重相加构成总的得分。

Table F1 Sample Appraisal Criteria for

Suitability Criteria	Description		Grading System
Appropriate device	Were the data generated from the device in question?	D1 D2 D3	Actual device Comparable device Other device
Appropriate device application	Was the device used for the same intended use (e.g., methods of deployment, application, etc.)?	A1 A2 A3	Same use Minor deviation Major deviation
Appropriate patient group	Were the data generated from a patient group that is representative of the intended treatment population (e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	P1 P2 P3	Applicable Limited Different population
Acceptable report/data collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1 R2 R3	High quality Minor deficiencies Insufficient information

表 F1 适宜性评估标准示例

适宜性标准	说明		分级系统
适当的器械	数据生成的器械来源？	D1 D2 D3	实际器械 比较器械 其他器械
适当的器械应用	器械是否用于相同的预期用途（即配置、应用方法等）？	A1 A2 A3	用途相同 轻微偏离 重大偏离
适当的患者组	数据是否来自可以代表预期治疗人群（例如，年龄、性别等）和临床状况（即，疾病，包含状态和严重度）的患者人群？	P1 P2 P3	适用 有限 不同人群
可接受的报告 / 数据收集	报告或者数据整理是否包含实施合理的、客观的评估所需要的足够信息？	R1 R2 R3	高质量 细微不足 信息不足

Table F2 Sample Appraisal Criteria for Data Contribution

Data Contribution Criteria	Description	Grading System	
Data source type	Was the design of the study appropriate?	T1 T2	Yes No
Outcome measures	Do the outcome measures reported reflect the intended performance of the device?	O1 O2	Yes No
Follow up	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1 F2	Yes No
Statistical significance	Has a statistical analysis of the data been provided and is it appropriate?	S1 S2	Yes No
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	C1 C2	Yes No

表 F2 数据贡献评估标准示例

数据贡献标准	说明	分级系统	
数据来源类型	研究的设计是否适当？	T1 T2	是 否
结果指标	报告的结果指标是否反映了器械的预期性能？	O1 O2	是 否
随访	随访期限是否足以评价治疗过程中是否有效果并识别并发症？	F1 F2	是 否
统计意义	是否提供了数据的统计分析以及该分析是否适当？	S1 S2	是 否
临床意义	观察到的治疗效果的量级是否具有临床意义？	C1 C2	是 否

.

Appendix G: A Possible Format for a Clinical Evaluation Report
附件 G：临床评价报告的一种可能格式

1 General details/基本情况

State the proprietary name of the device and any code names assigned during device development.
阐明器械所有人的名称以及器械研发过程中分配的代码名称。

Identify the manufacturer(s) of the device.
识别器械的生产商。

2 Description of the device and its intended application /器械及其预期应用的描述

Provide a concise physical description of the device, cross referencing to relevant sections of the manufacturer's technical information as appropriate. The description should cover information such as:
对器械进行准确的实质描述，如果合适，对照参考生产商技术信息的有关章节。描述应包括以下信息：

- materials, including whether it incorporates a medicinal substance (already on the market or new), tissues, or blood products;
- 材料，包括是否包含药物成分（市场已有或者新的）、组织或者血液制品；
- the device components, including software and accessories;
- 器械组成，包括软件与附件；
- mechanical characteristics; and
- 机械特征；以及
- others, such as sterile vs. non-sterile, radioactivity etc.
- 其他情况，如无菌 / 非灭菌、放射性等

State the intended application of the device – single use/reusable; invasive/non invasive; implantable; duration of use or contact with the body; organs, tissues or body fluids contacted by the device.
注明器械的预期应用—一次性使用 / 可重复使用；侵入 / 非侵入；可植入；使用或者与人体接触的时间；与器械接触的器官、组织或者体液。

Describe how the device achieves its intended purpose.
说明器械如何达到其预期用途。

3 Intended therapeutic and/or diagnostic indications and claims/ 预期治疗及／或诊断适应症和宣称

State the medical conditions to be treated, including target treatment group and diseases. Outline any specific safety, clinical performance and/or effectiveness claims made for the device
阐明治疗的状况，包括目标治疗人群以及疾病。概述该器械相关的所有具体安全性、临床性能和／或有效性宣称

4 Context of the evaluation and choice of clinical data types /评价内容和临床数据类型的选择

Outline the developmental context for the device. The information should include whether the device is based on a new technology, a new clinical application of an existing technology, or the result of incremental change of an existing technology. The amount of information will differ according to the history of the technology. Where a completely new technology has been developed, this section would need to give an overview of the developmental process and the points in the development cycle at which clinical data have been generated. For long standing technology, a shorter description of the history of the technology (with appropriate references) could be used. Clearly state if the clinical data used in the evaluation are for a comparable device. Identify the comparable device(s) and provide a justification of the comparability, cross- referenced to the relevant non-clinical documentation that supports the claim.

概述器械的研发背景。信息应包括器械是基于一项新技术、现有技术的新应用还是现有技术渐进性改变的结果。根据技术的发展历史不用，信息量也有所不同。在属于开发一项全新的新技术情况下，本章需要对开发过程以及产生临床数据的开发周期中的关键点进行总体描述。对于长期成熟技术，可对该技术的历史（具有适当的参考文件）进行简短叙述。应该清晰注明评价所用的临床数据是否来自对比器械。识别对比器械并提供可比性的理由，交叉引用支持其宣称的有关非临床文档。

State the Essential Principles relevant to the device in question, in particular, any special design features that pose special performance or safety concerns (e.g. presence of medicinal, human or animal components) that were identified in the device risk management documentation and that required assessment from a clinical perspective.
阐明与拟评价器械有关的基本原则，尤其是产生特殊性能或者安全性问题（即存在药物、人体或者动物成分）的特殊设计特征应在器械风险管理文档中予以识别，并需要在临床角度进行评价。

Outline how these considerations were used to choose the types of clinical data used for the evaluation. Where published scientific literature has been used, provide a brief outline of the searching/retrieval process, cross-referenced to the literature search protocol and reports.
概述在选择评价所用的临床数据类型时对这些因素是如何考虑的。在使用已发表的科学文献的情况下，概要说明查询／检索程序，并交叉引用文献检索方案和报告。

5 Summary of the clinical data and appraisal/ 临床数据总结与评估

Provide a tabulation of the clinical data used in the evaluation, categorized according to whether the data address the safety, clinical performance and/or effectiveness of the device in question. (Note: many individual data sets will address safety, clinical performance and/or effectiveness.) Within each category, order the data according to the importance of their contribution to establishing the safety, clinical performance and/or effectiveness of the device and in relation to any specific claims about safety, clinical performance and/or effectiveness. Additionally, provide a brief outline of the data appraisal methods used in the evaluation, including any weighting criteria, and a summary of the key results.

提供评价使用的临床数据的表格，根据数据证明拟评价器械的安全性、临床性能和/或有效性进行归类。（备注：很多单独的数据集同时解决安全性、临床性能和／或有效性问题。）在每一类型之中，根据数据对证明器械安全性、临床性能和／或有效性的贡献、以及对安全性、临床性能和／或有效性具体宣称的贡献的重要程度排列。另外，还应提供评价所用的数据评估方法，包括加权标准以及主要结果的总结。

Include full citations for literature-based data and the titles and investigation codes (if relevant) of any clinical investigation reports.
应包括基于文献的数据的完整引文以及所有临床试验报告的名称和研试验代码（如适用）。

Cross-reference the entry for each piece of data to its location in the manufacturer's technical documentation.
交叉引用生产商技术文档中每一数据所在的条目。

6 Data analysis/数据分析

6.1 Performance/性能

Provide a description of the analysis used to assess performance.
对评估性能所用的分析方法进行说明。

Identify the datasets that are considered to be the most important in contributing to the demonstration of the overall performance of the device and, where useful, particular performance characteristics. Outline why they are considered to be "pivotal" and how they demonstrate the performance of the device collectively (e.g. consistency of results, statistical significance, clinically significance of effects).
识别在证明器械总体性能、以及器械的特殊性能特征中，被认为最重要的数据集。概述认为这些数据集"关键"的原因以及这些数据集是如何共同证明器械的性能（即结果的一致性、效果的统计意义和临床意义）。

6.2 Safety/安全性

Describe the total experience with the device, including numbers and characteristics of patients exposed to the device; and duration of follow-up of device recipients
说明器械的全部临床经验，包括暴露于器械下的患者数量以及特征；器械使用者的随访持续时间。

Provide a summary of device-related adverse events, paying particular attention to serious adverse events.
提供器械相关不良事件的总结，对严重不良事件给予特别关注。

Provide specific comment on whether the safety characteristics and intended purpose of the device requires training of the end-user.
就是否需要对最终用户进行器械安全性特性和预期用途的相关培训进行专门评价。

6.3 Product Literature and Instructions for Use/产品资料与使用说明书

State whether the manufacturer's proposed product literature and Instructions for Use are consistent with the clinical data and cover all the hazards and other clinically relevant information that may impact on the use of the device.
阐明生产商提出的产品资料以及使用说明书是否与临床数据一致，是否包括所有危害以及可能影响器械使用的其他临床相关信息。

7 Conclusions/结论

Outline clearly the conclusions reached about the safety, clinical performance and/or effectiveness of the device from the evaluation, with respect to the intended use of the device. State whether the risks identified in the risk management documentation have been addressed by the clinical data.

明确概述通过评价得出的关于器械用于其预期用途的安全性、临床性能和／或有效性的结论。阐明在风险管理文档中识别的风险是否通过临床数据已得到解决。

For each proposed clinical indication state whether:
对于每种提出的临床适应症，应阐明：

- the clinical evidence demonstrates conformity with relevant Essential Principles;
- 临床证据是否证明符合相关基本原则；
- the safety, clinical performance and/or effectiveness of the device as claimed have been established; and
- 所宣称的器械安全性、临床性能和／或有效性是否已成立；以及
- the risks associated with the use of the device are acceptable when weighed against the benefits to the patient

1755 • 在与患者受益比较时，与器械使用相关的风险是否在可接受的范围之内。
1756