IMDRF MDCE WG (PD1)/N57 (GHTF/SG5/N3:2010)

WORKING DRAFT DOCUMENT
工作草案
International Medical Device Regulators Forum
国际医疗器械监管机构论坛

Title: Clinical Evidence – Key Definitions and Concepts
标题：临床证据-主要定义和概念

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Date: 1st February2019
日期：2019 年 2 月 1 日

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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. The document has been subject to consultation throughout its development.
本文件由国际医疗器械监管机构论坛(IMDRF)制定，该论坛是由来自世界各地的医疗器械监管机构组成的自愿小组。该文件在制定过程中始终在征求意见。

1. Introduction / 引言

It is anticipated that convergence of requirements for clinical evidence, including common data submissions, will lead to better understanding of medical device safety, clinical performance, and/or effectiveness by all stakeholders, more efficient use of resources of the clinical community, medical device regulators and industry, and increased transparency and confidence in the global regulatory model. Ultimately, there should be more efficient, predictable and timely access to safe and effective medical technology by patients and society worldwide.
临床证据要求的趋同，包括提交通用的数据，将可能会使所有的利益相关者更好地认识医疗器械的安全性、临床性能和/或有效性，更有效地利用临床社区、医疗器械监管者及行业的资源，并增加全球监管模式的透明度及信心。最后，世界范围内的患者及社会应当以更有效的、可预测的方式及时地接触到安全有效的医疗技术。

Clinical evidence and the Essential Principles of safety and performance of medical devices /临床证据与医疗器械安全及性能的基本原则

The IMDRF *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices* (the Essential Principles) set out the requirements relating to the safety and performance of medical devices. Of these, Essential Principles 5.1.1, 5.1.6, 5.1.7 and 5.1.9 in particular require that a medical device achieve its intended performance during normal conditions of use and that the known, and foreseeable risks, and any undesirable side-effects, are minimised and acceptable when weighed against the benefits of the intended performance.
IMDRF《医疗器械及 IVD 医疗器械安全及性能的基本原则》（基本原则）提出了与医疗器械安全及性能相关的要求。这些要求中的，基本原则 5.1.1, 5.1.6, 5.1.7 及 5.1.9 特别要求，正常使用时，医疗器械能够在已知的、可预见的风险及任何不良反应下，达到其预期性能，且与预期表现带来的受益相比，风险和不良反应很低且可以接受。

The diversity of medical devices and the technologies on which they are based pose special challenges for manufacturers, conformity assessment bodies and regulators alike when trying to identify what should constitute evidence sufficient to demonstrate compliance with the Essential Principles. Some technologies have been available for many years and are well characterised from a safety, clinical performance, and/or effectiveness viewpoint. On the other hand, many devices utilise new, state-of-the-art technology that has had little prior application in the treatment of humans.
医疗器械的多样性及其应用的技术，在生产商、认证机构及监管者判断已有证据是否足以证明与基本原则符合时，构成了特殊的挑战。一些技术已使用了多年，并且从安全性、临床性能、和/或有效性角度来说有着良好的表现。另一方面，许多器械使用新的、最先进的技术，之前却很少应用于患者的治疗。

Furthermore, their intended purpose and clinical application can vary widely with end results influenced by a wide range of different and differently experienced end-users.
而且，受到广泛的不同范围和不同经验的终端用户的影响，预期目的及临床应用的最终结果可能大不相同。

Given the complexity of the medical devices milieu, the assessment of what is acceptable

clinical evidence for the purpose of demonstrating compliance with the Essential Principles must be undertaken on a case-by-case basis. To this end, it is important to have an understanding of how medical devices are brought to market and of the role that clinical data and its evaluation plays in this process.
由于医疗器械应用环境的复杂性，在评估临床证据是否符合基本原则时，必须进行个案分析。因此，了解医疗器械如何进入市场，以及临床数据及临床评价在此过程中所起的作用，是非常重要的。

This document supersedes an earlier version produced under the Global Harmonization Task Force (GHTF) with the same title in May, 2007(GHTF/SG5/N1R8:2007).
本文件取代 2007 年 5 月全球协调工作组（GHTF）制定的同一标题的早期版本（GHTF/SG5/N1R8:2007）。

2. Scope / 范围

This document is intended to:
本文件旨在：

- introduce the concepts of clinical evaluation and clinical evidence;
  介绍临床评价及临床证据的概念；
- examine the relationship between clinical investigation, clinical data, clinical evaluation and clinical evidence; and
- 探讨临床研究、临床数据、临床评价以及临床证据之间的关系；和
- serve as guidance to all those involved in the generation, compilation and review of clinical evidence sufficient to support the marketing of medical devices (regulatory authorities, conformity assessment bodies, manufacturers of medical devices and their associated industry groups).
- 作为指南服务于生成、汇编及审评临床证据是否充分支持上市要求的相关人员或机构（监管当局、认证机构、医疗器械生产商及相关的行业团体）。

The definitions and concepts contained within this document are intended to apply to the establishment and maintenance of conformity with the relevant Essential Principles for medical devices generally. Specific guidance will be developed in other documents in relation to *in vitro* diagnostic devices. Similarly, guidance about how to generate, compile and present clinical evidence for the purpose of demonstrating compliance with the Essential Principles for safety and performance of a medical device will be addressed in future documents.
本文件中所包含的定义与概念旨在应用于建立并维护与医疗器械相关基本原则的符合性。关于体外诊断器械在其它文件中制定了专门的指南。同样，有关如何生成、汇编及呈现临床证据以证明其符合《医疗器械安全及性能基本原则》，将在后续的文件中予以解决。

3. References / 参考文献

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

IMDRF GRRP WG/N47 FINAL: 2018 *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Device*
IMDRF GRRP WG/N47 FINAL: 2018《医疗器械及 IVD 医疗器械安全和性能基本原

则》

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》

International standards/ 国际标准

ISO 14155-2011 *Clinical investigation of medical devices for human subjects — Good clinical practice*
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

4. Definitions and Concepts / 定义及概念

4.1 Clinical investigation / 临床试验

Definition: 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.
定义: 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。

Explanation: This term is synonymous with 'clinical trial' and 'clinical study'.
解释: 本术语与"临床试验"及"临床研究"同义。

An effective medical device has the ability to provide clinically significant results in a significant portion of the target population; effectiveness is established using documented scientific evidence that a medical device is effective.
有效的医疗器械能够在很大部分目标人群中展现出具有重要临床意义的结果；其有效性的建立应可通过书面的科学证据证明器械是有效的。

Clinical investigations include feasibility studies and those conducted for the purpose of gaining market approval, as well as investigations conducted following marketing approval.
临床试验包括可行性试验、为获得上市批准而进行的试验，以及在上市批准后开展的试验。

4.2 Clinical data / 临床数据

Definition: Safety, clinical performance, and/or effectiveness information that is generated from the clinical use of a medical device.
定义: 在临床使用过程中医疗器械所产生的安全性、临床性能、和/或有效性信息。

Explanation: Sources of clinical data may include:
解释: 临床数据来源可以包括：

(i) results of pre- and post-market clinical investigation(s) of the device concerned
相关器械的上市前和上市后临床试验结果；

(ii) results of pre- and post-market clinical investigation(s) or other studies reported in the scientific literature of a justifiably comparable device
适当的对比器械的上市前和上市后的临床试验结果，或者在科学文献上发表的其他研究结果；

(iii) published and/or unpublished reports on clinical experience of either the device in question or a justifiably comparable device
已发表和/或未发表的拟评价器械或适当的对比器械的临床经验报告；

(iv) other sources of clinical experience such as registries and adverse event databases
其他临床经验来源，如登记研究和不良事件数据库。

4.3 Clinical evaluation / 临床评价

Definition: 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.

定义： 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。

Explanation: This is a process undertaken by manufacturers of medical devices to help establish compliance with the relevant Essential Principles for safety and performance. The result of this process is a report that can be reviewed by conformity assessment bodies and regulators and which details the extent of available data and its quality and demonstrates how the compliance with the Essential Principles is satisfied by the clinical data. Clinical evaluation is an ongoing process - information about safety and clinical performance, and/or effectiveness (e.g. adverse event reports, results from any further clinical investigations, published literature etc.) should be monitored routinely by the manufacturer once the device is available on the market and the benefits and risks reassessed in light of this additional information.

解释： 这是一个由医疗器械生产商实施的，旨在帮助器械建立其安全性及性能符合相关基本原则的过程。此过程的结果是一份详细地介绍已有数据的程度及质量，并说明临床数据如何满足基本原则的要求，以用于认证机构和监管者的审评工作的报告。临床评价是一个持续进行的过程，器械上市后，有关安全性、临床性能和/或有效性的信息（例如不良事件报告、来自任何进一步临床试验的结果，出版的文献等）就应当常规性地由生产商进行监控，并且要根据新的信息对受益与风险进行重新评价。

Effectiveness is established using documented scientific evidence that a medical device is effective.
有效性的建立应可通过书面的科学证据证明器械是有效的。

The inputs for clinical evaluation are primarily clinical data in the form of clinical investigation reports, literature reports/reviews and clinical

experience. The data required to establish the initial evidence of compliance with the Essential Principles may vary according to the characteristics of the device, its intended use, the claims made by the manufacturer, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. A key goal of the clinical evaluation is to establish that any risks associated with the use of the device are acceptable when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. The clinical evaluation will, therefore, also need to cross-reference risk management documents.
临床评价的输入主要是以临床试验报告、文献报告/综述，及临床经验形式所包含的临床数据。根据器械的特征、预期的用途、生产商所宣称的内容，警示与其它限制是否存在及是否合适，以及使用经验的水平，用于建立器械与基本原则的符合性的初步证据所要求的数据各不相同。临床评价的主要目标，是确定与器械使用相关的任何风险，与患者的受益相比是可接受的，并且能相当程度地保护健康及安全。因此临床评价是需要与风险管理文件相互参照。

4.4 Clinical evidence／临床证据

Definition: The clinical data and the clinical evaluation report pertaining to a medical device.
定义： 与医疗器械相关的临床数据和临床评价报告。

Explanation: Clinical evidence is an important component of the technical documentation of a medical device, which 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. It should be cross-referenced to other relevant parts of the technical documentation that impact on its interpretation.
解释： 临床证据是医疗器械技术文件的重要组成部分，与设计验证及确认文件、产品描述、标签、风险分析及生产信息共同被生产商用于证明器械符合基本原则的要求。临床证据也应与技术文档中其他影响其解释的相关内容相互参照。

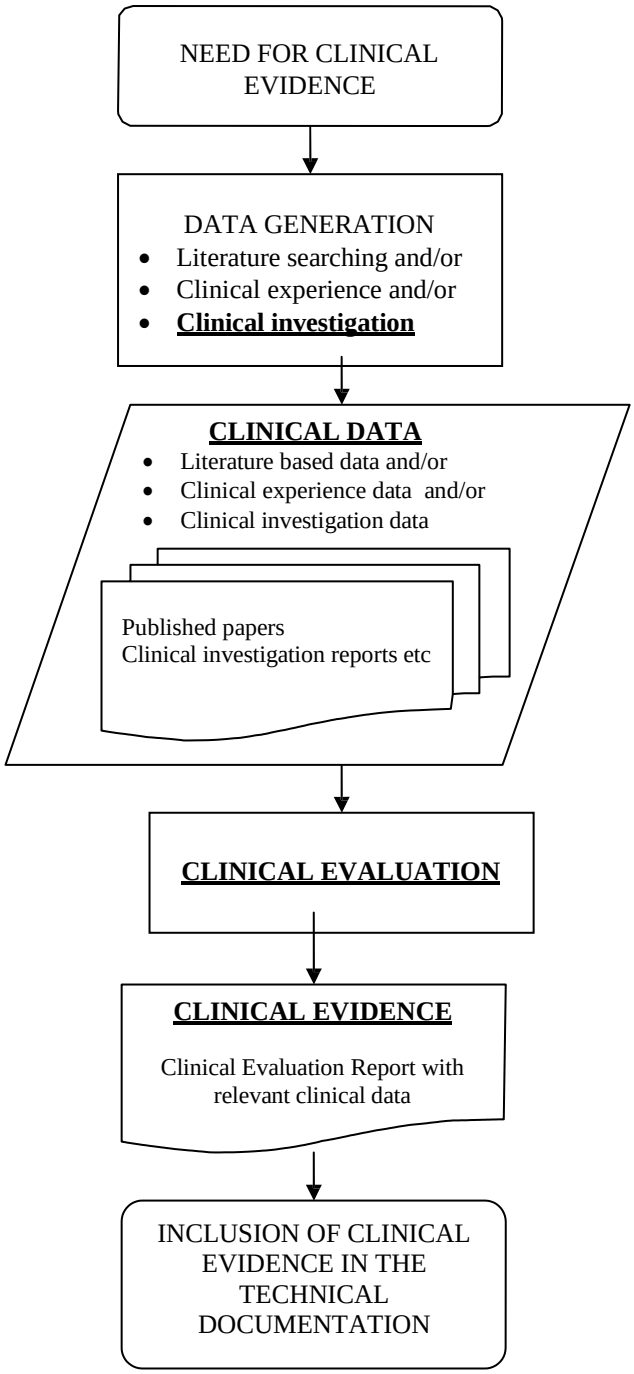
In accordance with applicable local regulations, clinical evidence, in part or in total, may be submitted to and reviewed by conformity assessment bodies and regulatory authorities. The clinical evidence is used to support the marketing of the device, including any claims made about the safety, clinical performance, and/or effectiveness of the device, and the labelling of the device. Figure 1 shows how the need for clinical evidence drives the processes of data generation and clinical evaluation, which produce clinical data and clinical evidence, respectively.
根据适用的当地法规，部分或全部临床证据可能会提交给认证机构和监管部门审评。临床证据可用于支持器械的上市，包括关于安全性、临床性能、和/或有效性以及标签信息中的任何相关宣称。图 1 展示了临床证据的需求是如何推动数据的生成以及临床评价的过程，相对应地分别产

生了临床数据和临床证据。

Clinical evidence should be reviewed and updated throughout the product life cycle by the manufacturer as new information relating to safety, clinical performance, and/or effectiveness is obtained from clinical experience during marketing (e.g. adverse event reports, results from any further clinical investigations, formal post market surveillance studies) of the device in question and/or comparable devices.

生产商应在整个产品生命周期中评估并更新临床证据，因为在器械在市场应用过程中，会通过临床经验获得关于该器械和/或其对比器械安全性、临床性能、和/或有效性的新信息（例如不良事件报告、任何进一步的临床试验结果，正式的上市后监督研究）。

Figure 1 Overview of process for data generation and clinical evaluation



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