Introduction: “Clinical Decision Support Software”
Draft Guidance for Industry and Food and Drug Administration Staff
FDA「臨床決策輔助軟體」指引草案 簡介

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報告內容

“Clinical Decision Support Software”

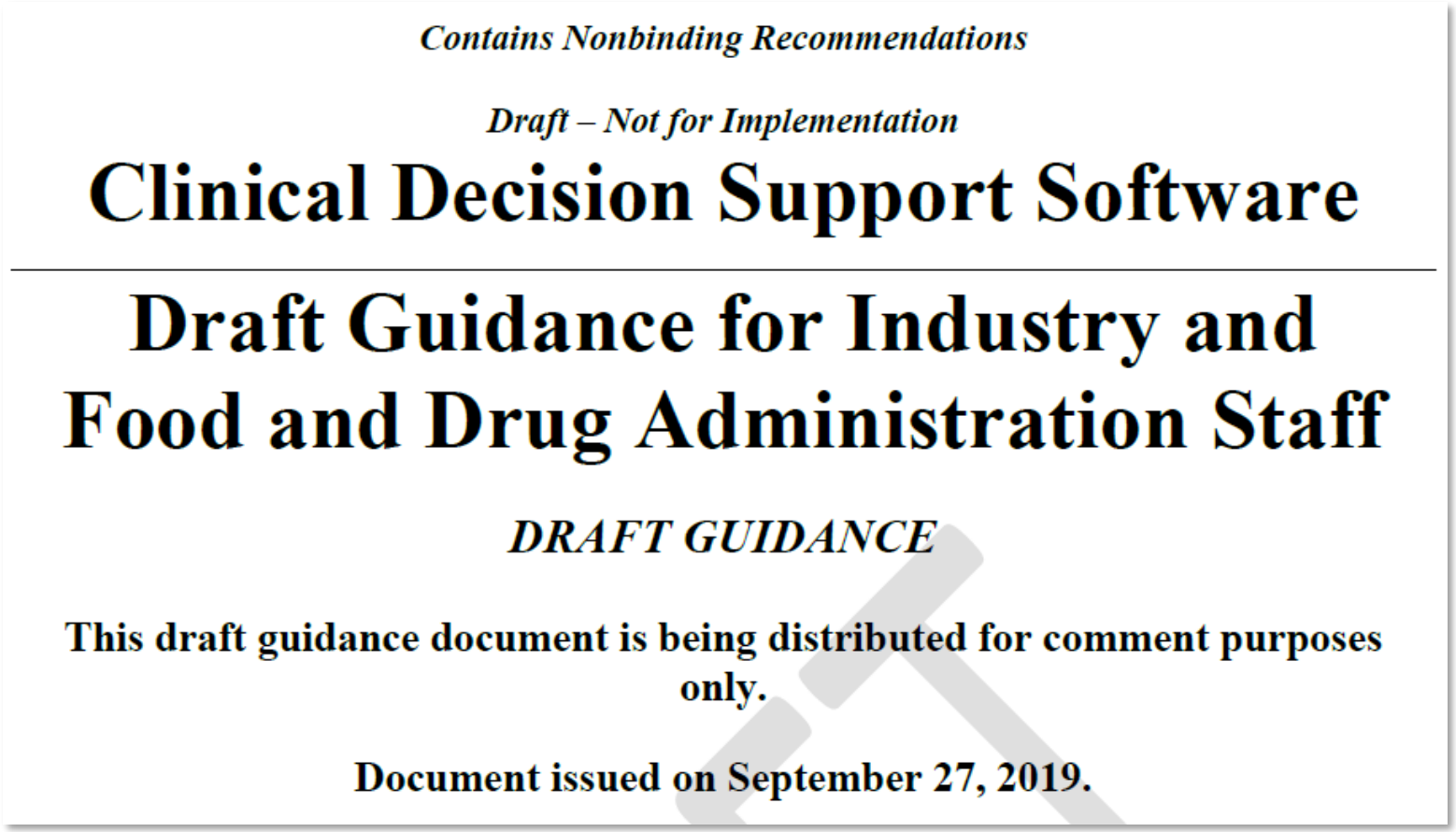
Draft Guidance for Industry and Food and Drug Administration Staff

「臨床決策輔助軟體」指引草案

- 簡介
- 法規依據與國際機制
- 詞彙解釋 (SaMD, CDS, Device)
- CDS 相關定義與適用範圍
- Section 520(o)(1)(E) 法條對於 Non-Device CDS 的判斷標準
- IMDRF 風險分類的運用
- 各類別 CDS 舉例說明
- 指引文件間的一致化

「臨床決策輔助軟體」指引草案 – 簡介

此指引文件未來將指導**產業**以及**美國食品藥品監督管理局職員** (FDA Staff) 承辦



Contains Nonbinding Recommendations

Draft – Not for Implementation

Clinical Decision Support Software

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

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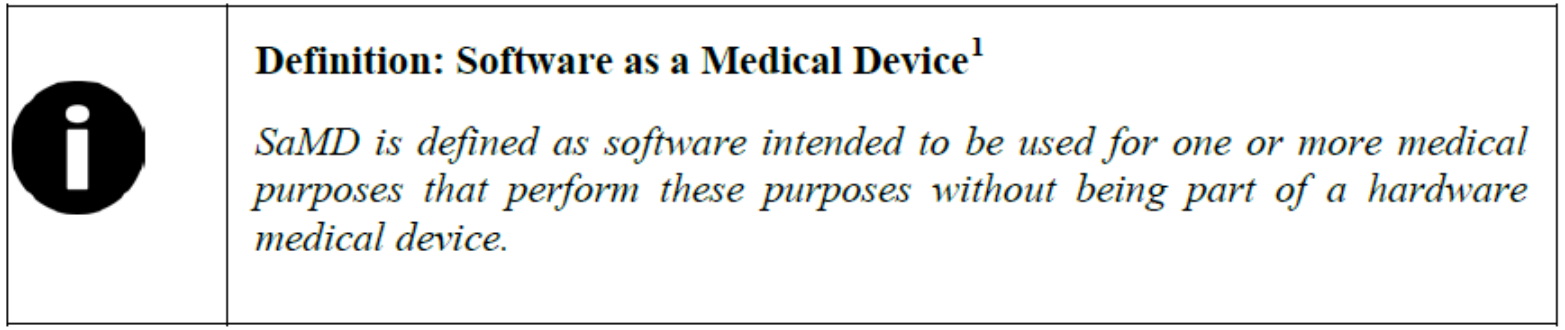
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software

法規依據與國際機制

法律與國際機制	日期	說明
21st Century Cures Act **21 世紀醫療法案 (Cures Act)** https://www.congress.gov/bill/114th-congress/house-bill/34 • section 3060(a)	Dec. 13, 2016 (法律) Public Law No: 114-255	• section 3060 清楚解釋醫療軟體法規。 • section 3060(a) 對於 FD&C Act 進行修訂，增列 section 520(o) 法條。
Federal Food, Drug, and Cosmetic Act **聯邦食品、藥品和化妝品法案 (FD&C Act)** https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act • section 201(h) • section 520(o)(1)(E)	June 24, 2019 (修訂) June 25, 1938 (法律) Public Law No: 75-717	• section 201(h) 定義 “device” (器材)。FDA 管控著 201(h) 所定義器材的軟體。 • section 520(o) 是醫療及某些特定決策輔助軟體的法規。 • section 520(o)(1)(E) 說明使用於 device 的軟體可以有哪些目的，譬如：顯示醫療資訊。
International Medical Device Regulators Forum Framework **國際醫療器材管理論壇機制 (IMDRF) Framework** http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf • "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations • software as a medical device (SaMD)	Sept. 18, 2014 (公佈)	IMDRF 機制包含兩個重要因素： A. SaMD 提供的資訊，對於醫療決策的含義，包括：治療或診斷、驅動臨床管理、通知臨床管理。 B. 病人醫療照護情形的狀態： critical 危急的、serious 嚴重的、 non-serious 不嚴重的。

詞彙解釋 (1)

- **Software as a Medical Device (SaMD) (軟體作為醫療設備)**
  - https://www.fda.gov/medical-devices/digital-health/software-medical-device-samd



Definition: Software as a Medical Device[1]

SaMD is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.

IMDRF Framework

- **Clinical Decision Support (CDS) (臨床決策輔助)**
  - https://www.healthit.gov/topic/safety/clinical-decision-support
  - CDS is described as ***a variety of tools*** including, but not limited to: computerized alerts and reminders for providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support; and contextually relevant reference information. (CDS 是各種工具，包含但不限於：給供應者以及病人電腦化的警示及提醒，臨床準則，特定情況的訂單組套，重點性的病人資料報告及概要，文件模板，診斷輔助，以及上下文相關的參考資訊。)
  - The term "CDS" is used to refer to functions that are either **Device CDS** or **Non-Device CDS**. FDA uses criteria from the 21st Century Cures Act (Cures Act) to determine if a software function is Device CDS or Non-Device CDS.

詞彙解釋 (2)

- **Device (器材)** (section 201(h) of the FD&C Act)

(h) Device (器材) (除了其他所列法條款項所使用到的 device 意思之外) 的意思是指一個儀器、裝置設備、工具、機器、發明物、植入物、體外試劑、或其他類似或相關的物品，包含任何組成零件、部件、附件，

(h) The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).

CDS 相關定義與適用範圍 (1)

This guidance provides many examples of how FDA intends to regulate different kinds of software functions, including:

- Non-Device CDS functions;
- Device CDS functions for which, based on our current understanding of the risks of these devices, FDA intends at this time not to enforce compliance with applicable requirements;
- Device CDS functions on which FDA intends to focus its regulatory oversight; and
- Non-CDS device functions on which FDA intends to focus its regulatory oversight.

FDA 計畫要規範的軟體功能種類：

- **非器材類** CDS 功能。
- 基於當前所了解到的器材風險，對於某些**器材類** CDS 功能，FDA 目前不強制遵循其施行 (FD&C Act) 的必要。
- FDA 計畫要將重點放在於規範某些**器材類** CDS 功能的監管責任。
- FDA 計畫要將重點放在於規範某些**非器材類** CDS 功能的監管責任。

CDS 相關定義與適用範圍 (2)

A software function is considered CDS, for the purposes of this guidance, if it meets the following:

- Not intended to acquire, process, or analyze [criterion (1)];
- Intended for the purpose of displaying, analyzing, or printing medical information [criterion (2)]; and
- Intended for the purpose of supporting or providing recommendations [part of criterion (3)].

如果符合下列要求，基於此指引所述及的目的，此軟體功能是認定為 CDS：

- 並不企圖去取得、處理、或分析資料。 *(section 520(o)(1)(E) of the FD& C Act 判斷標準 1)*
- 企圖將會顯示、分析、或列印醫療資訊。 *(section 520(o)(1)(E) of the FD& C Act 判斷標準 2)*
- 企圖將會輔助或提供推薦訊息。 *(section 520(o)(1)(E) of the FD& C Act 判斷標準 3 的部分)*

CDS 相關定義與適用範圍 (3)

Table 1. Is a CDS Software Function Device or Non-Device?

Is the Intended User an HCP? [part of criteria (3) and (4)]	Can the User Independently Review the Basis?* [part of criterion (4)]	Is it Device CDS?
Yes	Yes	No, it is Non-Device CDS because it meets all of section 520(o)(1)(E) criteria
	No	Yes, it is Device CDS
No, it is a patient or caregiver	Yes	Yes, it is Device CDS
	No	Yes, it is Device CDS

- **HCP** (health care professionals) 醫療專業人員, **Patient** 病人, **Caregiver** 照顧者
- * "Can the User Independently Review the Basis?" 詢問是否此軟體功能是企圖要讓使用者可以獨立檢視推薦訊息的基礎原理，因此它並不是要讓使用者根深蒂固地依賴任何這樣的推薦訊息 (判斷標準 4 的部分)。
- 只有醫療專業人員會使用到 Non-Device CDS ，病人及照顧者只會使用到 Device CDS。

此指引文件表述目前 FDA 對於 CDS 的想法，規範方式，因使用者不同而有不同的區分及說明，也描述 FDA 並不做強制性規範的地方。

Section 520(o)(1)(E) 對於 Non-Device CDS 的判斷標準 (1)

對於一個軟體功能是 **Non-Device CDS** ，它必須都符合四個判斷標準，以排除在 section 520(o) of the FD&C Act 所定義下的 device 之外。

(1) Not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system

從體外診斷器材所產生出來的醫學影像或信號，或者從信號擷取系統產生出來的圖案或信號，Non-Device CDS 並不企圖去取得、處理、或分析這些資料。

說明：

根據 section 520(o)(1)(E)，當軟體功能企圖去取得、處理、或分析資料，而這些資料是由體外診斷器材所產生出來的醫學影像或信號，或者從信號擷取系統產生出來的圖案或信號，**這仍然是 section 201(h) of the FD&C Act 中對於 device 所制定的定義目的**，所以依然受到 FDA 的監管。

Section 520(o)(1)(E) 對於 Non-Device CDS 的判斷標準 (2)

(2) Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information

Non-Device CDS 企圖將會顯示、分析、或列印有關於病人的醫療資訊，或其他醫療資訊。

說明：

Section 520(o)(1)(E)(i) of the FD&C Act 所描述的軟體功能，是企圖顯示、分析、或列印有關於病人的醫療資訊，或其他醫療資訊 (例如：專業臨床研究和臨床實踐準則)。FDA 解釋認為包含這些軟體功能有顯示、分析、或列印病人特定的資訊，例如人口統計資訊、症狀、測試結果、醫療器材輸出信息 (例如：心律或血壓)、病人分泌物概要、以及或醫療資訊 (例如：臨床實踐準則、專業臨床研究、教科書、經認可的藥物或醫療器材標記、以及政府機構建議書)。

Section 520(o)(1)(E) 對於 Non-Device CDS 的判斷標準 (3)

(3) **Intended for the purpose of supporting or providing recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition**

Non-Device CDS 企圖將會輔助或提供推薦訊息給醫療專業人員，有關於預防、診斷、或治療疾病或症狀。

說明：

Section 520(o)(1)(E)(ii) 所描述的軟體功能，是企圖輔助或提供推薦訊息給醫療專業人員有關於預防、診斷、或治療疾病或症狀。這樣的功能企圖協助醫療專業人員做成特定病人的照護決策。(軟體功能輔助或提供推薦訊息給病人或照顧者，並不是 HCPs 醫療專業人員，這軟體功能仍然是在 Device 的定義中。)

Section 520(o)(1)(E) 對於 Non-Device CDS 的判斷標準 (4)

(4) Intended for the purpose of enabling an HCP to independently review the basis for the recommendations that such software presents so that it is not the intent that the HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient

Non-Device CDS 企圖將會使醫療專業人員可以獨立檢視其軟體所呈現推薦訊息的基礎原理，使得醫療專業人員不會根深蒂固地依賴任何這樣的推薦訊息，對於一個個別病人去進行臨床診斷或做治療決策。

說明：

Section 520(o)(1)(E)(iii) 說明到，在 section 520(o)(1)(E) of the FD&C Act 運作時，為了對於一個 Device 的定義排除在外，CDS 功能必須使醫療專業人員可以獨立檢視其軟體所呈現推薦訊息的基礎原理，使得他們不會根深蒂固地依賴這樣的推薦訊息，**而是根據他們自己的判斷**，對於個別病人做出臨床決策。

FDA interprets section 520(o)(1)(E)(iii) to mean that manufacturers of Non-Device CDS should describe their software functions in plain language, including:

1) The purpose or intended use of the software function;
2) The intended user (e.g., ultrasound technicians, vascular surgeons);
3) The inputs used to generate the recommendation (e.g., patient age and sex); and
4) The basis for rendering a recommendation.

IMDRF 風險分類的運用 *(Application of IMDRF Risk Categorization)* (1)

Table 2. SaMD Categories established in IMDRF Framework

State of health care situation or condition	Significance of information provided by SaMD to health care decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

Factor A

Factor B

- 利用 IMDRF 的機制，FDA 計畫要運用一個基於風險的政策至 Device CDS 功能的規範上。IMDRF 機制所適用的許多軟體功能比此指引所提及的 Device CDS 和 Non-Device CDS 功能多；FDA 使用部分的機制在 CDS 政策中。

- 對於一個 SaMD 的風險分類，IMDRF 機制描述兩個主要的因素：
  A. SaMD 提供的資訊，對於醫療決策的含義，包括：治療或診斷、驅動臨床管理、通知臨床管理。
  B. 病人醫療照護情形的狀態： critical 危急的、 serious 嚴重的、 non-serious 不嚴重的。

IMDRF 風險分類的運用 *(Application of IMDRF Risk Categorization)* (2)

Table 3. Summary of Regulatory Policy for CDS Software Functions

		Intended User is HCP		Intended User is Patient or Caregiver
IMDRF Risk Categorization	**Can the User Independently Review the Basis?***	**FDA Regulation**		**FDA Regulation**
Inform x Critical	Yes	Not a Device		Oversight Focus
	No	Oversight Focus		Oversight Focus
Inform x Serious	Yes	Not a Device		Oversight Focus
	No	Oversight Focus		Oversight Focus
Inform x Non-Serious	Yes	Not a Device		Enforcement Discretion**
	No	Enforcement Discretion**		Oversight Focus

FDA要規範監管責任

註解：

- * "Can the User Independently Review the Basis?" 詢問是否此軟體功能是企圖要讓使用者可以獨立檢視推薦訊息的基礎原理，因此它並不是要讓使用者根深蒂固地依賴任何這樣的推薦訊息 (判斷標準 4 的部分)。
- ** "Enforcement Discretion" (謹慎實施) 意思是，基於當前所了解到的器材風險，對於某些器材類 CDS 功能，FDA 目前不強制遵循其施行 (FD&C Act) 的必要。

CDS 舉例說明類別

A.	**Examples of Non-Device CDS Functions.**
	不符合 section 201(h) 中對於 device 所制定的定義，因為它們符合 section 520(o)(1)(E) 中所有四個判斷標準。Non-Device CDS 不考慮病人醫療照護情形的狀態 (critical 危急、serious 嚴重、non-serious 不嚴重)。
B.	**Examples of Device CDS for which, based on our current understanding of the risks of these devices, FDA does not intend at this time to enforce compliance with applicable device requirements.** (1) Device CDS intended for HCPs, (2) Device CDS intended for patients
	FDA 不強制遵循其施行 FD&C Act 的必要性，此類別 Device CDS 是不嚴重情況下的通知臨床管理 (“inform clinical management” for “non-serious situations or conditions”)。 • 其中給病人使用的部分，並且是企圖使病人可以獨立評估此軟體推薦訊息的基礎原理。
C.	**Device CDS on which FDA intends to focus its regulatory oversight.** (1) Device CDS intended for HCPs, (2) Device CDS intended for patients
	FDA 計畫要將重點放在於規範 Device CDS 功能的監管責任。 1) 醫療專業人員所使用的，是嚴重或危急情況下的通知臨床管理 (“inform …” for “serious or critical …”)，而且並不企圖使醫療專業人員可以獨立評估。 2) 病人所使用的，包含不嚴重情況下的通知臨床管理 (“inform …” for “non-serious …”)，不企圖使病人可以獨立評估；以及嚴重或危急情況下的通知臨床管理 (“inform …” for “serious or critical …”)，不管病人是否可以獨立評估。
D.	**Examples of device software functions that are not CDS on which FDA intends to focus its regulatory oversight.**
	FDA 計畫要將重點放在於規範不符合 Device CDS 定義的器材功能的監管責任，這些是醫療法案 (Cures Act) 中定義以及此指引中所使用的，但是是器材 (device)。

例子

A. Examples of Non-Device CDS Functions

- Software that provides recommendations to HCPs by matching patient-specific information (e.g., diagnosis, treatments, allergies, signs or symptoms) to reference information the medical community routinely uses in clinical practice (e.g., practice guidelines) to facilitate assessments of specific patients. The software explains that the basis of the recommendation is developed from authoritative medical sources, as recognized by the field or discipline that is the subject of the software and provides or cites those materials. Examples include:
    - Software that uses a patient's diagnosis to provide an HCP with current practice treatment guidelines for common illnesses or conditions such as influenza, and provides the source of the guidelines; and
    - Software that helps to identify drug-drug interaction and drug-allergy contraindications, based on the current version of FDA-approved drug or medical device labeling or other up-to-date and reliable sources and patient-specific information, to attempt to prevent adverse drug events.

軟體藉由配對病人特定的資訊 (例如：診斷、治療、過敏反應、徵兆或症狀) 至臨床實踐中所使用的醫療團體日常使用的參考資訊 (例如：實踐準則)，以評估特定病人，而**提供給醫療專業人員推薦訊息**。此軟體解釋推薦訊息的基礎原理是從權威性的醫療來源開發而來，而且經由此軟體所涉及主題以及提供或引用材料的此領域或學科所認可。例子包括：

- 對於常見的疾病或症狀，例如流行性感冒，軟體使用一位病人的診斷去**提供一位醫療專業人員當前實踐治療準則**，以及**提供準則的來源出處**。
- **軟體幫助辨別**藥與藥之間的交互作用，以及藥與過敏反應的禁忌症，是**基於 FDA 所認可過的**藥物或醫療器材標記的當前版本，或基於較新的可靠來源以及病人特定資訊，**以期避免有害的藥物事態**。

例子

B. Examples of Device CDS for which, based on our current understanding of the risks of these devices, FDA does not intend at this time to enforce compliance with applicable device requirements

(1) Device CDS intended for HCPs

- Software that provides recommendations of potential allergens and common cold symptoms based on location-specific electronic health records, environmental conditions, and patient-reported outcomes to provide the HCP with options for different diagnoses (e.g., seasonal allergic rhinitis vs. common cold). This software is a Device CDS function, because the HCP is not intended to be able to independently evaluate the basis for the software's recommendations. At this time, FDA does not intend to enforce compliance with applicable requirements of the FD&C Act for this Device CDS, because it is an aggregation of data intended to provide clinical information for a non-serious situation or condition (i.e., "inform x non-serious").

根據特定地區的電子衛生紀錄、環境條件、以及病人報告結果，軟體**提供推薦訊息給醫療專業人員有差異化的診斷選項** (例如：季節性過敏性鼻炎 vs. 常見感冒)。這個軟體是一個 **Device CDS 功能**，因為**醫療專業人員並不期望可以獨立評估此軟體推薦訊息的基礎原理**。目前，FDA 對於此 Device CDS，不強制遵循其施行 FD&C Act 的必要性；因為它是一個資料的收集，企圖**提供**有關於**非嚴重性情況或條件**的**臨床資訊**。

例子 B.

(2) Device CDS intended for patients

- Software that assists a patient in identifying OTC cold or allergy medications to consider purchasing based on symptoms. For example, once a patient or non-HCP caregiver inputs the symptoms of the person needing a cold or allergy medication, the software provides a prioritized list of OTC medications that match the person's symptoms. In this example, inclusion of appropriate warnings about products with overlapping active ingredients (e.g., multiple products containing acetaminophen) would be an important mechanism to prevent risks to patients that might arise from using this software. This software is Device CDS, because it is intended for a patient. At this time, FDA does not intend to enforce compliance with applicable requirements of the FD&C Act for this software function, because it is intended to provide options for the treatment of a non-serious situation or condition (i.e., "inform x non-serious") and because it is intended for the patient to be able to independently evaluate the basis for the software's recommendations.16

[16] Such information sources (identified by the software) may include FDA-approved labeling or DailyMed for drug labeling.

軟體協助病人，根據症狀去找出考慮要購買的非處方感冒藥物或過敏藥物 (OTC, over the counter 非處方)。例如，當病人或不是醫療專業人員的照顧者，輸入這個需要感冒或過敏藥物的人的症狀，這個軟體**提供有關於符合此人症狀的非處方藥物的優先順序列表**。在這個例子裡，包含有關於產品會產生交互作用的組成成分 (例如：多種產品含有 acetaminophen 乙醯氨酚) 的適當警告訊息是一個重要的機制，以避免病人可能經由使用這個軟體而增加風險。

這個軟體是 **Device CDS**，因為它是為了給病人使用的。目前，FDA 對於此軟體功能，不強制遵循其施行 FD&C Act 的必要性；因為它是企圖**提供**有關於**非嚴重性情況或條件**的治療選項，而且因為它是**企圖使病人可以獨立評估此軟體推薦訊息的基礎原理**。

註解：由軟體所找出的這樣的資訊來源，可能包括經由 FDA 所認可的標記或者 DailyMed 對於藥物的標記。

例子

C. Device CDS on which FDA intends to focus its regulatory oversight

(1) Device CDS intended for HCPs

- Machine-learning algorithm, for which the logic and inputs are not explained, that categorizes likely symptoms of seasonal influenza for each flu season based on location and current electronic health records of patients diagnosed or suspected to have influenza to assist HCPs in differentiating between common flu symptoms and other illnesses (e.g., common cold) in a particular season. This software is a Device CDS function, because the HCP is not expected to be able to independently evaluate the basis for the software's recommendations. FDA intends to focus its regulatory oversight on this software, because it is intended to inform clinical management for a serious situation or condition.
    - Note: If the HCP could evaluate the basis for the software's recommendations, because the logic and inputs for the machine-learning algorithm and data inputs used for the algorithm were explained and available to the HCP, then this software would be considered Non-Device CDS (Section VII.A).

某機器學習演算法，並沒有解釋它的邏輯和輸入，是根據地區資料、以及經診斷或疑似有流行性感冒的病人現在的電子衛生紀錄，去進行分類每一個流感季節的季節性流感性感冒的可能症狀，以**協助醫療專業人員在特定季節去辨別常見的流感症狀與其他疾病** (例如：常見感冒)。這個軟體是一個 **Device CDS 功能**，因為**醫療專業人員並不期望可以獨立評估此軟體推薦訊息的基礎原理**。FDA 計畫要將**重點放在規範對於這類軟體的監管責任**，因為它企圖**通知臨床管理**一個**嚴重性**的情況或條件。

- 注意：如果醫療專業人員可以評估此軟體推薦訊息的基礎原理，因為此機器學習演算法的邏輯和輸入，以及使用於此演算法的資料輸入是經過解釋的，而且協助醫療專業人員可以獲得，則這個軟體會被視為 Non-Device CDS。

例子 C.

(2) Device CDS intended for patients

- Software that aggregates data from continuous glucose monitoring, activity trackers, and food logs to help insulin-dependent type 2 diabetic patients identify potential lifestyle triggers for hypoglycemic events and recommends corrective treatment options (e.g., timing of insulin dosing). This software is a Device CDS function, because it is intended for patients and to inform clinical management. FDA intends to focus its regulatory oversight on this software, because it is intended to inform clinical management for a serious situation or condition.

軟體從持續的血糖監測、活動機能追蹤、飲食紀錄等處收集資料，去**幫助胰島素依賴第二型糖尿病患者辨認引發低血糖狀態的潛在生活方式誘因**，以及**推薦矯正的療法選項** (例如：胰島素劑量的時間掌控)。這個軟體是一個 **Device CDS 功能**，因為它是為了給病人使用的，以及通知臨床管理。FDA 計畫要將**重點放在規範對於這類軟體的監管責任**，因為它企圖**通知臨床管理**一個**嚴重性**的情況或條件。

例子

D. Examples of device software functions that are not CDS on which FDA intends to focus its regulatory oversight

- Software that uses a patient's image sets (e.g., CT, magnetic resonance (MR)) to create an individual treatment plan for review by an HCP for patients undergoing radiation therapy treatment with external beam or brachytherapy. This software is a device function, because this software is intended to analyze a medical image and to generate the treatment plan, which is intended to guide the next treatment intervention.

軟體使用一個病人的影像資料組 (例如：CT 、磁共振) 去建立一個個別的治療計畫，使得醫療專業人員可以檢閱，以使病人接受外部射線或內照射放療法的放射治療。這個軟體是一個器材功能，因為此軟體企圖分析一個醫學影像，以及去產生治療計畫，企圖去**指導干預下一次治療**。(drive clinical management)

- Software that manipulates or analyzes images and other data obtained from a radiological device (e.g., CT, bone density, and distance) to create 3D models of the region intended to be used in planning orthopedic/dental surgical treatments with a device. This software is a device function, because this software is intended to analyze a medical image and to generate the models for planning treatment.

軟體操作或分析從放射性器材所獲得的影像以及其他資料 (例如：CT 骨質密度)，去建立身體部位的 3D 模型，企圖要在一個器材中規劃使用整形外科或牙科的外科手術治療。這個軟體是一個器材功能，因為此軟體企圖分析一個醫學影像，以及去**產生模型以規劃治療**。(drive clinical management)

FDA 指引文件間的一致化

VIII. Conforming Changes to Existing Guidance

Once this guidance is finalized, FDA intends to make conforming edits to the FDA Guidance Policy for Device Software Functions and Mobile Medical Applications [19] to make it consistent with the interpretations and policies in this guidance. For example, software functions that use patient characteristics such as age, sex, and behavioral risk factors to provide patient-specific screening, counseling, and preventative recommendations from well-known and established authorities (listed in Appendix B of the guidance) are not devices.

當此指引文件定版後，FDA 將促使另一指引文件「器材軟體功能與行動醫療應用的政策」一致化，以符合此指引文件中的解釋與政策。

謝謝指教！