



# Cortellis Regulatory Intelligence

## デジタルヘルス関連規制文書の抽出と 新規文書のモニタリング方法

クラリベイト

# Cortellis Regulatory Intelligence - デジタルヘルス関連規制文書の検索例

## 手順1. “eHealth” Topicフィルターを使用してデジタルヘルス関連規制文書をリストアップする

1. 検索ボックス下の“Filter”から  
“Topic” > “eHealth”を選択して“Apply”で確定

Search

Document title, topic, country, reference

Search Advanced search

Filter

Country/Region Topic Document Type Document Category Date Filter Last Updated All other filters Reset Filters

Select all Clear all Sort by Frequency

Other Topic (10400) Prescription Requirements (8674) Pediatrics (7752) Import Export (6549) Fees (6145)

Active Pharmaceutical Ingredient (5270) Pricing Reimbursement HTAs (4758) Orphan Products (4252)

Advertising and Promotion (3995) Non Clinical Studies (3178) Environment (2402) eHealth (1658)

Cancel Apply

## 2. 必要に応じて検索キーワードやフィルター項目を追加し、 “Search”をクリックして検索を実行します (ここでは“Country/Region” > “USA”フィルターを追加)

最後に“Search”をクリック

Search

Document title, topic, country, reference

Search Advanced search

Filter

Country/Region Topic Document Type Document Category Date Filter Last Updated All other filters Reset Filters

USA

## 3. “Topic”の索引である“eHealth”が付与された、 デジタルヘルス関連の米国の文書がリストアップされます

Regulatory > All Results

1,145 results

Switch to Comparison Tables

Drugs & Biologics Medical Devices & IVDs

Refine Search

Side by Side Viewer

Showing 1-10 of 1,145 results

Customize Columns Sorted by Relevance

Summary	Title	Abstract	Reason for
28-Aug-2009 V US EN RD	94644 - Federal Register: Blood Establishment Computer Software: Understanding What to Include in a 510(k) Submission; Public Workshop (Notice of pub	The Food and Drug Administration (FDA) is announcing a public workshop entitled “Blood Establishment Computer Software:	N/A
1-Jun-2009 V US EN RD	91868 - GAO Report: Privacy and Security: Food and Drug Administration Faces Challenges in Establishing Protections for Its Postmarket Risk Analysis	This report evaluate the Sentinel project (postmarket risk identification and analysis system based on electronic health data)of	N/A
17-Apr-2009 V US EN RD	90783 - DHHS Press Release: HHS Releases Guidance for Securing Health Information and Preventing Harm from Breaches - 17-Apr-2009	Issued on April 17, 2009, this document informs about the publication of a guidance regarding technologies and methodologies	N/A
20-Mar-2009 V US EN RD	90010 - DHHS Press Release: HHS Names David Blumenthal As National Coordinator for Health Information Technology - 20-Mar-2009	On March 20, 2009, the Department of Health and Human Services announced the selection of David Blumenthal, M.D., M.P.P.	N/A

eHealthの索引付け対象例：Mobile medical applications, Telemedicine, Artificial Intelligence, Electronic Health Record, Wireless Medical Device, Software as a Medical Device等に関する規制文書

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## 手順2. “Refine Search”で更にキーワードやフィルターを追加して絞り込み可能

### 4. 検索キーワードを追加してみます 例：SaMD or “Software as a Medical Device”

Regulatory > All Results  
1,145 results  
Switch to Comparison Tables

Drugs & Biologics  Medical Devices & IVDs

**Refine Search機能**

Refine Search ^ Include Outdated ? My Regions ?

SaMD or "Software as a Medical Device" Search

Filter  
Country/Region Topic Document Type Document Category Date Filter Last Updated

Searchをクリックして追加条件を適用

Side by Side Viewer Showing 1-10 of 1,145 results

Customize Columns Sorted by Relevance

Summary	Title	Abstract	Reason for
<input checked="" type="checkbox"/> 28-Aug-2009 <span>V</span> <span>US</span> <span>EN</span> <span>RD</span>	94644 - Federal Register: Blood Establishment Computer Software: Understanding What to Include in a 510(k) Submission; Public Workshop (Notice of pub	The Food and Drug Administration (FDA) is announcing a public workshop entitled "Blood Establishment Computer Software:	N/A

### 5. 検索結果の絞り込みが完了しました 1,145件→74件

Regulatory > All Results  
75 results for 'SaMD or "Software as a Medical Device"'  
Switch to Comparison Tables

Drugs & Biologics  Medical Devices & IVDs

Refine Search ^ Include Outdated ? My Regions ?

SaMD or "Software as a Medical Device" Search

Filter  
Country/Region Topic Document Type Document Category Date Filter Last Updated All other filters Reset Filters

Side by Side Viewer Showing 1-10 of 75 results

Customize Columns Sorted by Relevance

Summary	Title	Abstract	Reason for
<input checked="" type="checkbox"/> 08-Dec-2017 <span>V</span> <span>US</span> <span>EN</span> <span>RD</span>	265892 - Guidance for Industry and Food and Drug Administration Staff: Software as a Medical Device (SAMD): Clinical Evaluation (Final) - 08-Dec-2017	This document is the fourth issued by the International Medical Device Regulatory Forum (IMDRF) that provides a path for	Formatting update con on 24-Jan-

### “eHealth” Topicの収録文書数（2022年2月時点）

- Drugs & Biologics: 約658
  - Medical Devices & IVDs: 約1,982
- （両モジュールでの重複収録あり、また購読されている国・地域によって閲覧できる文書数に違いがあります）

さらに検索結果に表示される文書のカテゴリを“Drugs & Biologics”または“Medical Devices & IVDs”関連の文書に絞ることも可能です（両モジュールをご利用中のユーザー様のみ）

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## 手順3. 検索条件にアラートを設定して新たな規制文書の出現をモニタリング (Save and Alert on Query)

6. 検索条件に合致する新たな規制文書の収録をモニターするためアラートを設定します

Search results for "SaMD or "Software as a Medical Device""

Filters:  Drugs & Biologics  Medical Devices & IVDs

Include Outdated  My Regions

Search

Topic Document Type Document Category Date Filter Last Updated All other filters Reset Filters

Showing 1-10 of 75 results

Sorted by Relevance

Title	Abstract	Reason
265892 - Guidance for Industry and Food and Drug Administration Staff: Software as a Medical Device (SaMD): Clinical Evaluation (Final) - 08-Dec-2017	This document is the fourth issued by the International Medical Device Regulatory Forum (IMDRF) that provides a path for	Formatting update on 24-Jan-

7. アラート条件を確認し"Save"で設定を完了すると、今後、検索条件に合致する新たな文書の出現をメールで通知します

Save Search Query

Title: SaMD or "Software as a Medical Devi...06-Apr-2021 08:26

Details

Query: SaMD or "Software as a Medical Device"

Content Set: Regulatory

Filters: 3 Filters Applied

Create Alert

Cancel Save

 検索結果画面のベルのアイコンをクリックして Save and Alert onメニューから"Query"を選択します。

"Save"をクリックするとすぐにDaily Alertの設定が完了します。"Create Alert"の右側の▼をクリックすると、アラート頻度等の詳細設定が可能です。

※アラート設定の詳細はCortellis Regulatory Intelligence ユーザーガイドをご参照ください

(<https://clarivate.com/cortellis/ja/download/50426/>)