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Cortellis Regulatory Intelligence
入門編 トレーニングウェビナー

世界の最新規制情報を効率的に収集し追跡するには？

クラリベイト ライフサイエンス&ヘルスケア | 2025年6月19日 13:00-13:50

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1. Cortellis Regulatory Intelligence
データベース概要

規制対応におけるお客様の課題

薬事・臨床開発・薬制・安全性監視・製造・品質・CMC・市場アクセス etc. 様々な業務で・・・

規制情報の入手

日常業務に追われる中で、多くの国の規制文書を簡単、確実に入手したい。

規制変更のモニタリング

新たな規制情報の発出や、規制の変更をタイムリーに漏れなく監視したい。

言語の壁

読めない言語の規制対応を迅速かつ低コストで実現したい。

規制の理解

規制文書を全部読むのは大変、各国の規制の枠組みや実務を短時間で理解したい。

複数国の規制対応

効率的に規制対応を進めるために、各国で異なる規制情報を比較したい。

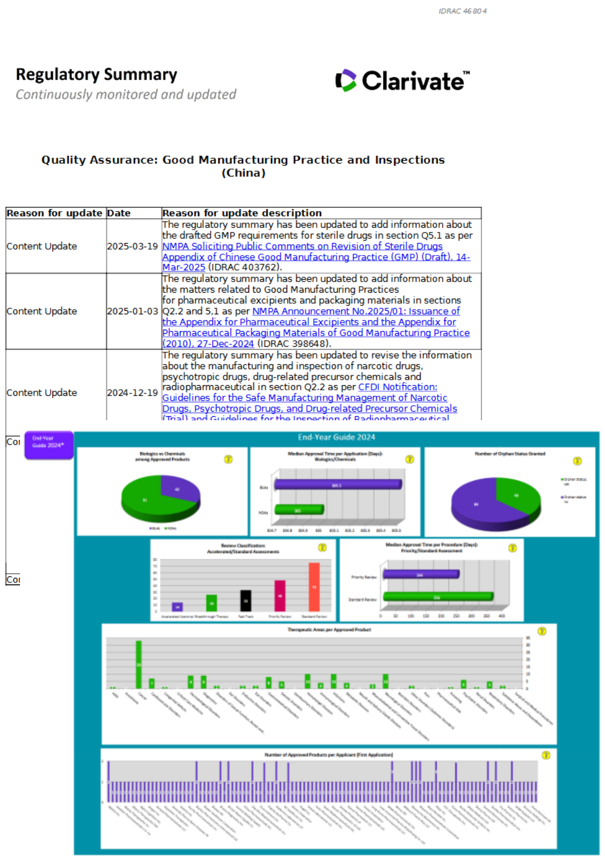
先行事例調査

当局対応や先行事例分析を効率よく実施したい。

現在お使いの規制文書情報源で、情報入手・分析に投資した時間とコストに見合う、確実な結果をタイムリーに得られていますか？

Cortellis Regulatory Intelligence

医薬品・医療機器・体外診断薬のライフサイクル全体をカバーする**網羅的な薬事規制情報**データベース



IDRAC 46 80 4

Regulatory Summary

Continuously monitored and updated

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Quality Assurance: Good Manufacturing Practice and Inspections (China)

Reason for update	Date	Reason for update description
Content Update	2025-03-19	The regulatory summary has been updated to add information about the drafted GMP requirements for sterile drugs in section Q5.1 as per NMPA Soliciting Public Comments on Revision of Sterile Drugs Appendix of Chinese Good Manufacturing Practice (GMP) (Draft), 14-Mar-2025 (IDRAC 403762).
Content Update	2025-01-03	The regulatory summary has been updated to add information about the matters related to Good Manufacturing Practices for pharmaceutical excipients and packaging materials in sections Q2.2 and 5,1 as per NMPA Announcement No.2025/01: Issuance of the Appendix for Pharmaceutical Excipients and the Appendix for Pharmaceutical Packaging Materials of Good Manufacturing Practice (2010), 27-Dec-2024 (IDRAC 398648).
Content Update	2024-12-19	The regulatory summary has been updated to revise the information about the manufacturing and inspection of narcotic drugs, psychotropic drugs, drug-related precursor chemicals and radiopharmaceutical in section Q2.2 as per CFDI Notification: Guidelines for the Safe Manufacturing Management of Narcotic Drugs, Psychotropic Drugs, and Drug-related Precursor Chemicals (Trial) and Guidelines for the Inspection of Radiopharmaceutical

End-Year Guide 2024*
End-Year Guide 2024
Biologics vs Chemicals among Approved Products
Median Approval Time per Application (Days): Biologics/Chemicals
Number of Orphan Status Granted
Review Classification: Accelerated/Standard Assessments
Median Approval Time per Procedure (Days): Priority/Standard Assessment
Priority Review
Standard Review
Therapeutic Areas per Approved Product
Number of Approved Products per Applicant (First Application)

81
国と地域

287K+
規制文書

45K+
規制文書の英語翻訳

2K+
規制解説文書

7K+
規制の分析レポート

43各国規制の比較表

Top 25グローバル製薬企業の88%が採用

6K+
FDA査察関連文書

速報メールサービス

- **毎週月曜日に各国の規制最新情報をお届け**
- **FDA諮問委員会のサマリーレポートを即日配信**

（FDA諮問委員会サマリー配信はUSモジュールご契約の場合のみ）

利用事例の一部

- 新たな規制の出現や規制の変更を絶えず網羅的にモニタリングする
- 各国の医薬品新規申請および変更申請の要件、審査プロセス、承認までのタイムラインを把握する
- GMP認証プロセスやGMPガイドライン、査察要件の最新情報を入手する
- 競合品の審査報告書、リスク管理計画情報を入手し、自社品の申請戦略立案の参考にする
- 各国の薬価・保険償還を取り巻く制度、申請プロセスや、HTAの導入状況を確認する

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効率的な規制情報モニタリングとコンプライアンス維持のために

Cortellis Regulatory Intelligenceが各国規制の網羅的かつタイムリーな把握をサポートします

毎日更新されるデータベースで世界中の最新規制情報をタイムリーに把握

規制変更のモニタリングや複数国間の要件比較などの分析を効率化

非英語圏の言語の壁を越えて情報収集が可能

各国の規制専門家の知見を活用し、規制対応を迅速化

収録対象の国・地域

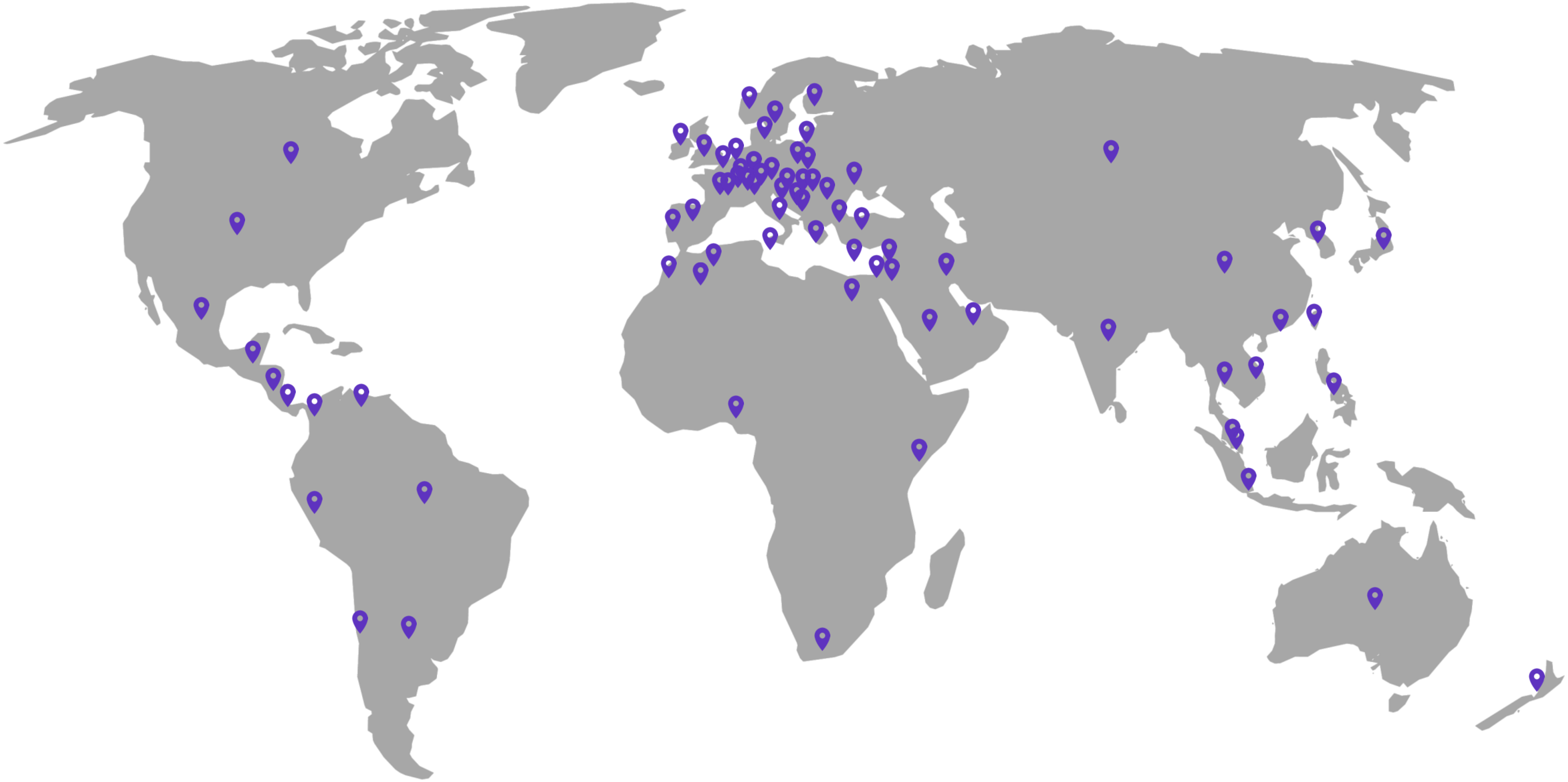
Cortellis Regulatory Intelligence

81

Drugs & biologics

75

Medical devices & IVDs



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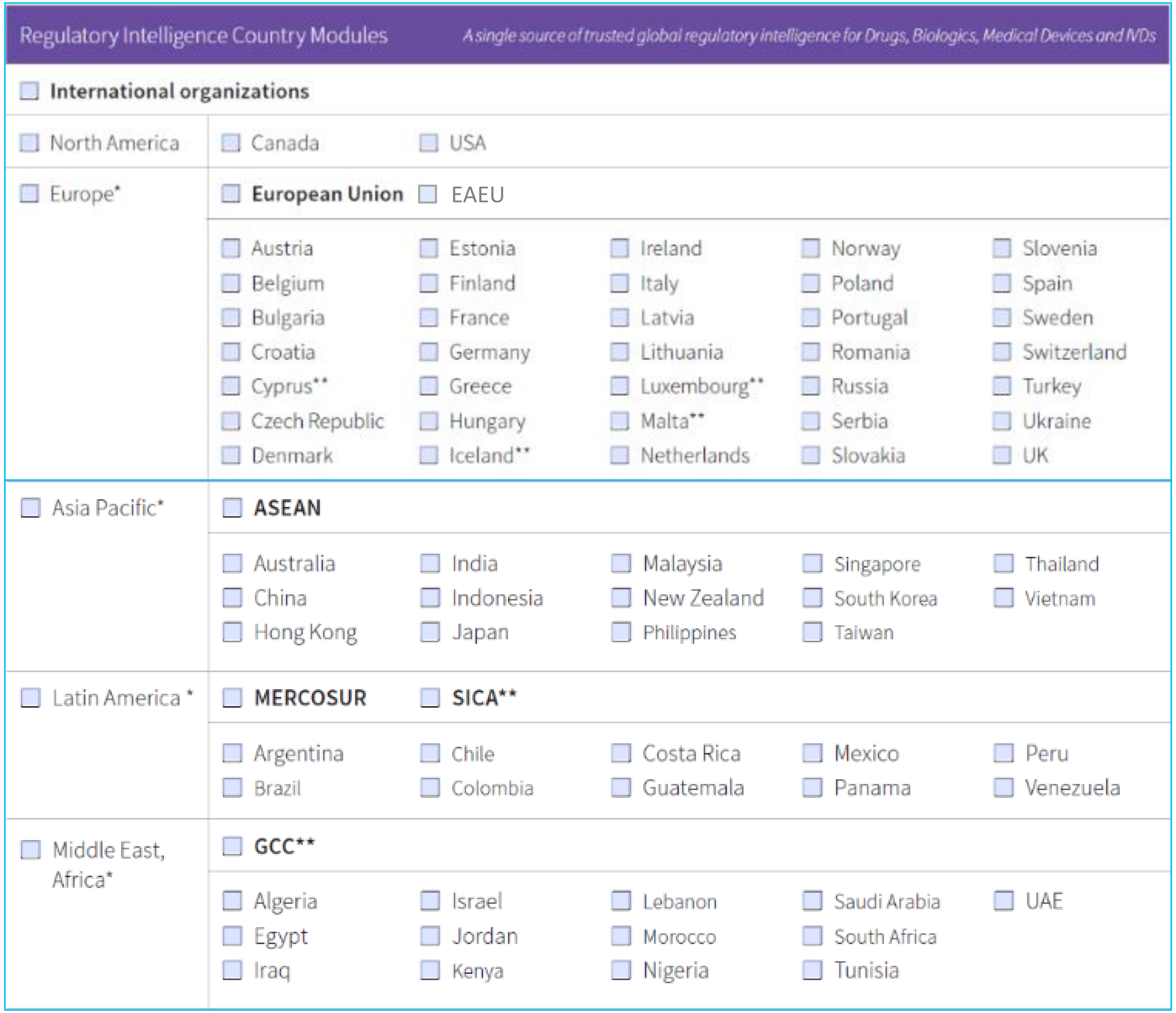
収録国一覧

81の国と地域



Regulatory Intelligence Country Modules

A single source of trusted global regulatory intelligence for Drugs, Biologics, Medical Devices and IVDs

☐ **International organizations**

☐ North America

☐ Canada
☐ USA

☐ Europe*

☐ **European Union**
☐ EAEU

☐ Austria
☐ Belgium
☐ Bulgaria
☐ Croatia
☐ Cyprus**
☐ Czech Republic
☐ Denmark
☐ Estonia
☐ Finland
☐ France
☐ Germany
☐ Greece
☐ Hungary
☐ Iceland**
☐ Ireland
☐ Italy
☐ Latvia
☐ Lithuania
☐ Luxembourg**
☐ Malta**
☐ Netherlands
☐ Norway
☐ Poland
☐ Portugal
☐ Romania
☐ Russia
☐ Serbia
☐ Slovakia
☐ Slovenia
☐ Spain
☐ Sweden
☐ Switzerland
☐ Turkey
☐ Ukraine
☐ UK

☐ Asia Pacific*

☐ **ASEAN**

☐ Australia
☐ China
☐ Hong Kong
☐ India
☐ Indonesia
☐ Japan
☐ Malaysia
☐ New Zealand
☐ Philippines
☐ Singapore
☐ South Korea
☐ Taiwan
☐ Thailand
☐ Vietnam

☐ Latin America *

☐ **MERCOSUR**
☐ **SICA****

☐ Argentina
☐ Brazil
☐ Chile
☐ Colombia
☐ Costa Rica
☐ Guatemala
☐ Mexico
☐ Panama
☐ Peru
☐ Venezuela

☐ Middle East, Africa*

☐ **GCC****

☐ Algeria
☐ Egypt
☐ Iraq
☐ Israel
☐ Jordan
☐ Kenya
☐ Lebanon
☐ Morocco
☐ Nigeria
☐ Saudi Arabia
☐ South Africa
☐ Tunisia
☐ UAE

International organizations:

- International Council for Harmonisation (ICH)
- European Directorate for the Quality of Medicines Council of Europe (EDQM-CoE)
- International Medical Device Regulators Forum (IMDRF)
- Pharmaceutical Inspection Co-operation Scheme (PIC/S)
- World Health Organization (WHO)
- World Health Organization Collaborating Centres (WHOCC)

薬事規制業務に必要な実用的なインサイト

Cortellis Regulatory Intelligenceの付加価値コンテンツ

Source Documents

- 世界各国の規制当局・機関の公式文書
- 最新および過去バージョンを蓄積（バージョン管理情報付与）
- 全ての規制文書に英語のタイトル・抄録・更新理由等付加
- 現地語文書に機械翻訳を付与
- さらに一部の国は専門家による全文英訳を追加
- Medical Devices & IVDs: 16カ国
  China, South Korea, Taiwan, Japan, Brazil, Mexico, Israel, Russia, Argentina, Austria, France, Germany, Italy, Spain, Switzerland, Turkey

Regulatory Summaries

- 薬事専門家による各国の規制の枠組み・プロセスの英語解説文
- 標準化されたフォーマット
- 主要な規制文書をリスト
- 規制変更により随時更新

Regulatory Intelligence Reports

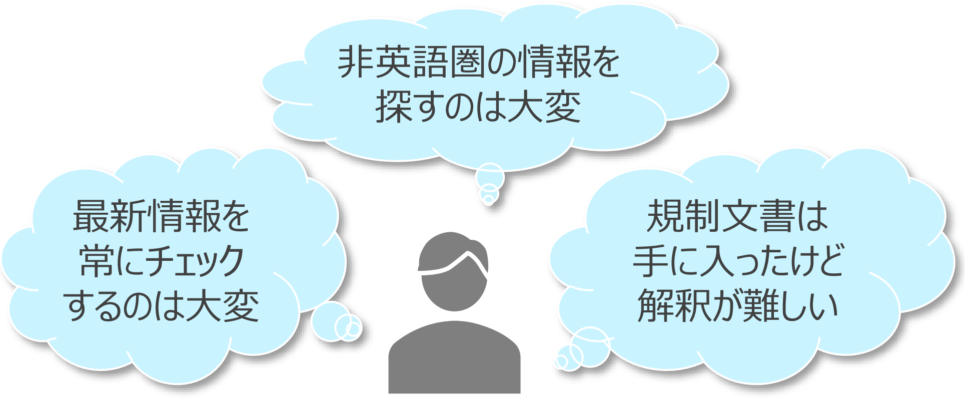
- 様々な重要トピックについて実務に役立つ規制分析レポート
  - 規制変更追跡
  - 競合品承認情報
  - FDA査察情報　等

Global Regulatory Comparisons

- 重要トピックに関する世界各国の規制比較表
- 規制の共通点・相違点を簡単に把握
- 主要な規制文書へのリンクで簡単に詳細を確認可能
- 随時更新

Cortellis Regulatory Intelligenceを活用するメリット

規制当局のウェブサイトを見ているけど…



非英語圏の情報を探すのは大変

最新情報を常にチェックするのは大変

規制文書は手に入ったけど解釈が難しい

現地のパートナーから情報が入ってくるけど…

自分でも現地の規制をある程度把握したい

必要な規制情報が全部揃っているか不安

最新規制情報の網羅性と速報性の強化

- 世界中の規制情報が集約され、最新情報が通知される

現地語の壁を超えた情報収集

- 各国規制の英語での解説レポートや、規制文書の英語翻訳を入手し、規制の理解を促進

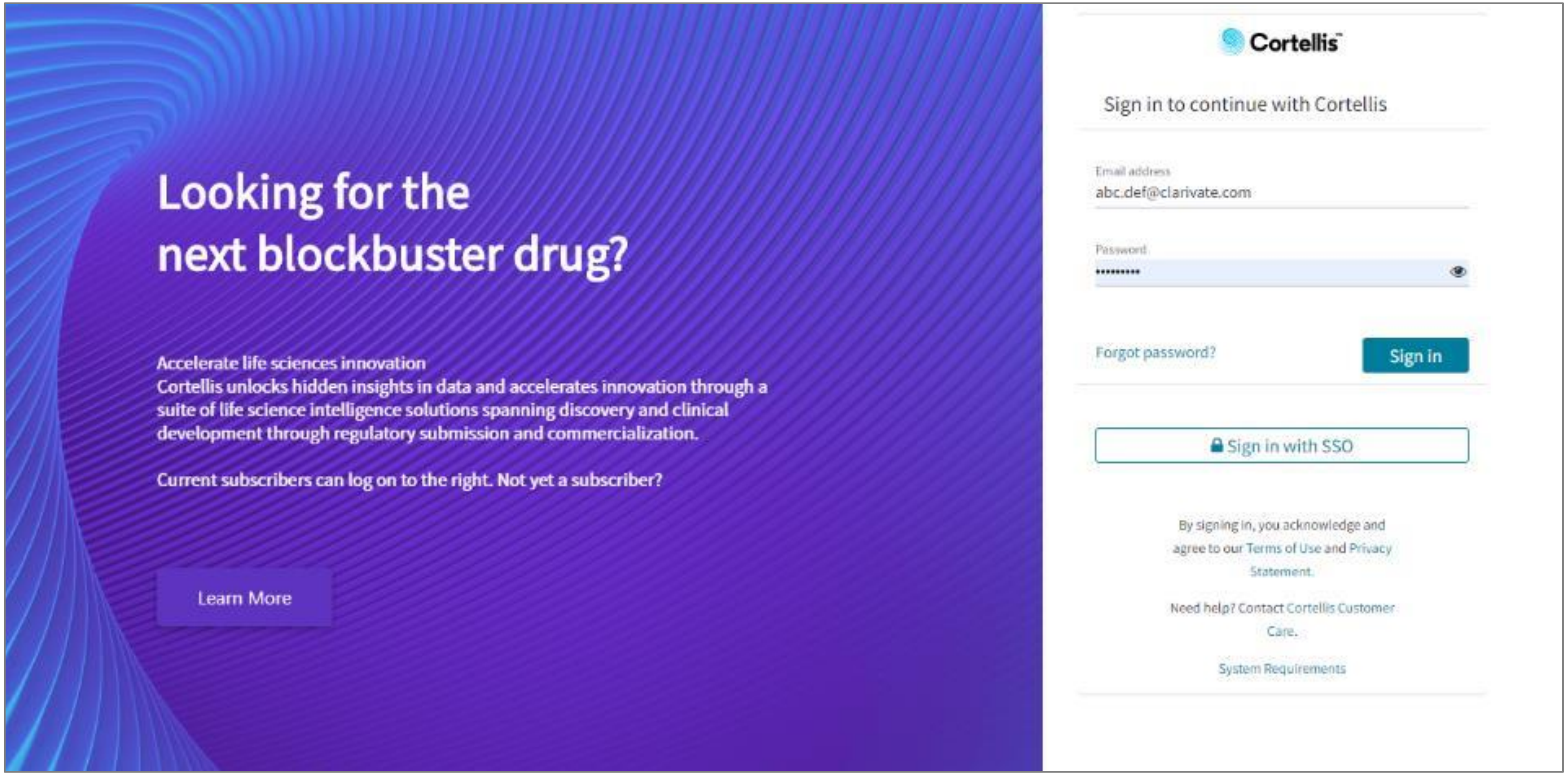
各国規制の理解・分析の効率向上

- 規制の理解・分析・各国比較に役立つコンテンツが豊富
- 各国の専門編集者・コンサルタントによるサポート体制

基本コンテンツ・機能へのアクセス方法

Cortellisへのアクセス

https://www.cortellis.com/intelligence



Looking for the
next blockbuster drug?

Accelerate life sciences innovation
Cortellis unlocks hidden insights in data and accelerates innovation through a suite of life science intelligence solutions spanning discovery and clinical development through regulatory submission and commercialization.

Current subscribers can log on to the right. Not yet a subscriber?

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Cortellis

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Email address
abc.def@clarivate.com

Password
••••••••••

Forgot password?
Sign in
Sign in with SSO

By signing in, you acknowledge and agree to our Terms of Use and Privacy Statement.

Need help? Contact Cortellis Customer Care.

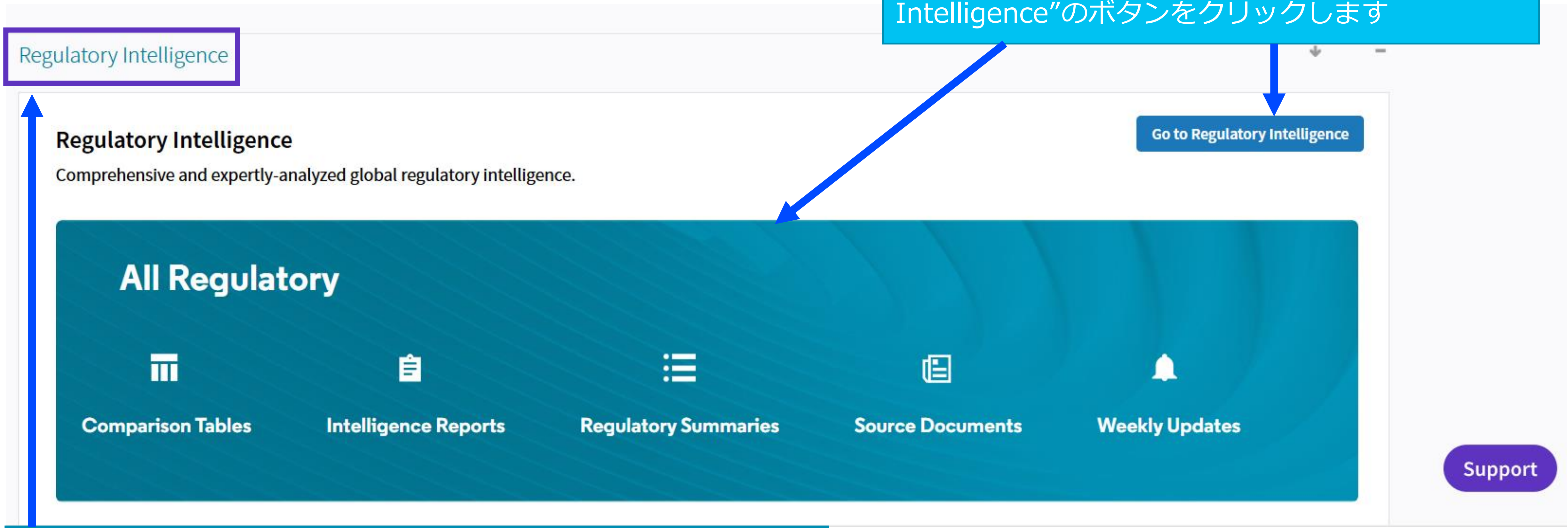
System Requirements

※SSO (Single Sign-On)アクセスのユーザ様はURLが異なります

Cortellis Regulatory Intelligenceホームページへのアクセス

CortellisログインのTOP画面

Cortellisにログイン後、Regulatory Intelligenceのパネル内のボタン、または”Go to Regulatory Intelligence”のボタンをクリックします


Regulatory Intelligence

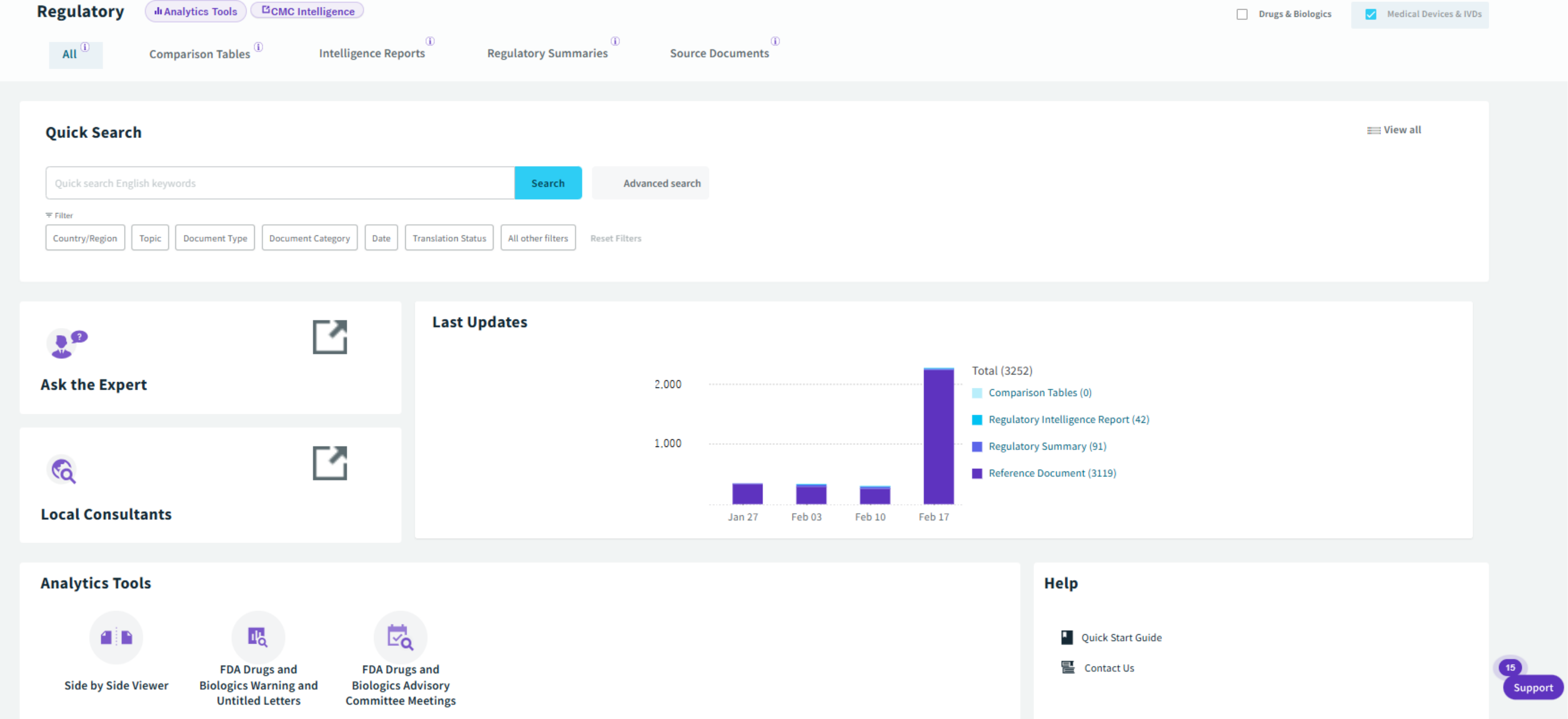
Regulatory Intelligence

Comprehensive and expertly-analyzed global regulatory intelligence.

Go to Regulatory Intelligence
All Regulatory
Comparison Tables
Intelligence Reports
Regulatory Summaries
Source Documents
Weekly Updates
Support

パネルが表示されていない場合は、”Regulatory Intelligence”の文字部分をクリックするとパネルが開きます

Regulatory Intelligence 専用のホームページ



Regulatory Analytics Tools CMC Intelligence

☐ Drugs & Biologics ☑ Medical Devices & IVDs

All | Comparison Tables | Intelligence Reports | Regulatory Summaries | Source Documents

Quick Search

View all

Quick search English keywords | Search | Advanced search

Filter

Country/Region | Topic | Document Type | Document Category | Date | Translation Status | All other filters | Reset Filters

Ask the Expert

Local Consultants

Last Updates

Total (3252)

- Comparison Tables (0)
- Regulatory Intelligence Report (42)
- Regulatory Summary (91)
- Reference Document (3119)

Analytics Tools

- Side by Side Viewer
- FDA Drugs and Biologics Warning and Untitled Letters
- FDA Drugs and Biologics Advisory Committee Meetings

Help

- Quick Start Guide
- Contact Us

15 Support

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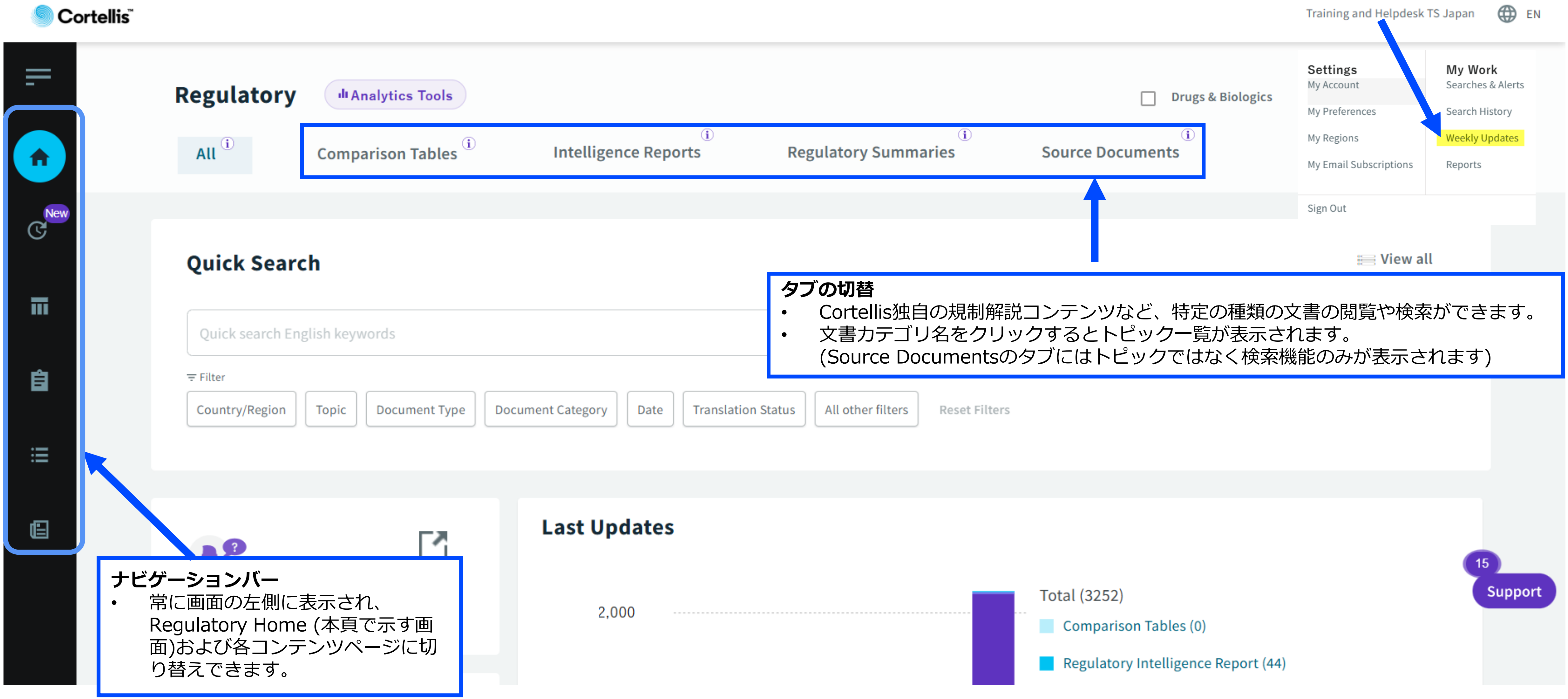
メインコンテンツへのアクセス

Weekly Alerts
- 自身のアカウント名をクリックし、最新および過去12週のWeekly AlertsをHTMLまたはExcelでダウンロードできます。


Cortellis
Training and Helpdesk TS Japan
EN
Regulatory
Analytics Tools
Drugs & Biologics
Settings
My Account
My Preferences
My Regions
My Email Subscriptions
My Work
Searches & Alerts
Search History
Weekly Updates
Reports
Sign Out
All
Comparison Tables
Intelligence Reports
Regulatory Summaries
Source Documents
New
Quick Search
View all
Quick search English keywords
Filter
Country/Region
Topic
Document Type
Document Category
Date
Translation Status
All other filters
Reset Filters
Last Updates
2,000
Total (3252)
Comparison Tables (0)
Regulatory Intelligence Report (44)
15
Support

タブの切替
- Cortellis独自の規制解説コンテンツなど、特定の種類の文書の閲覧や検索ができます。
- 文書カテゴリ名をクリックするとトピック一覧が表示されます。
(Source Documentsのタブにはトピックではなく検索機能のみが表示されます)

ナビゲーションバー
- 常に画面の左側に表示され、Regulatory Home (本頁で示す画面)および各コンテンツページに切り替えできます。

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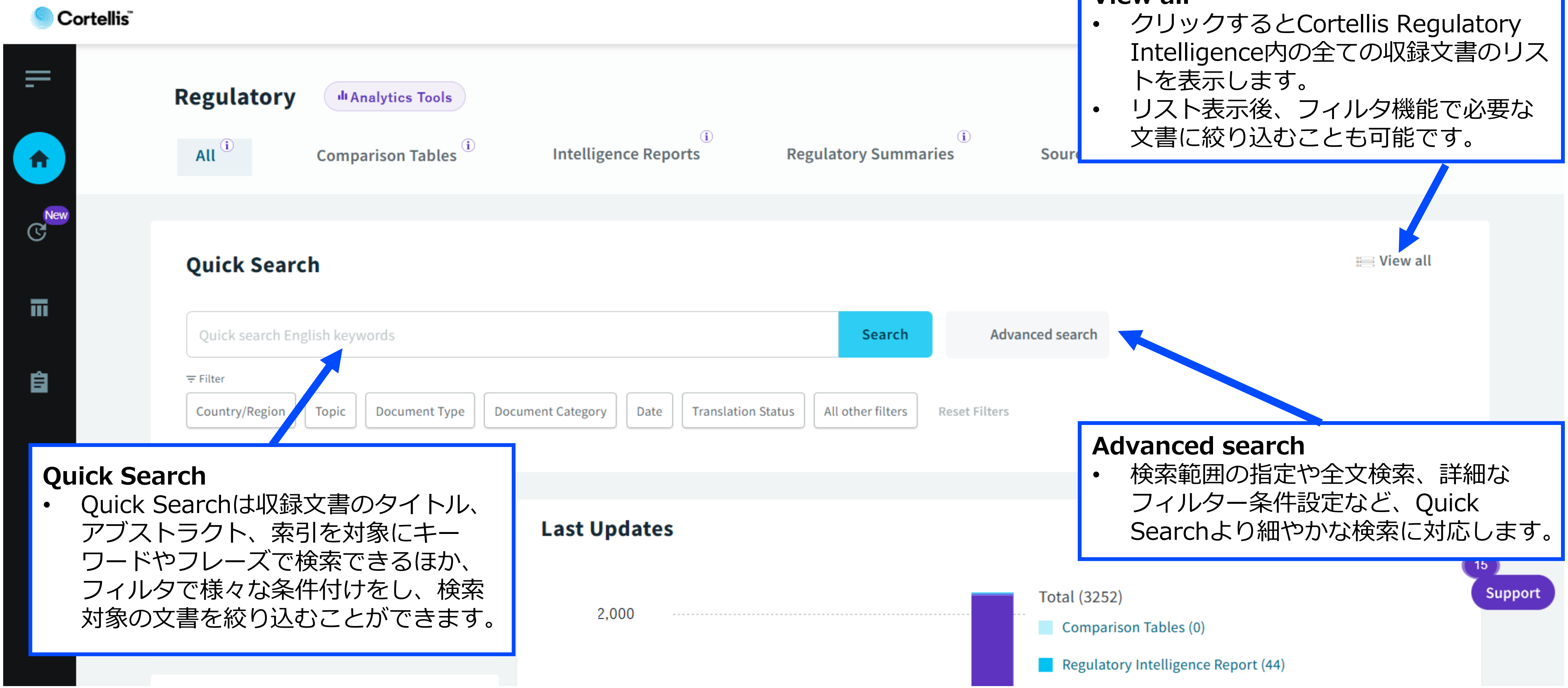
検索機能へのアクセス


Cortellis
Regulatory
Analytics Tools
All
Comparison Tables
Intelligence Reports
Regulatory Summaries
Sour
New
Quick Search
View all
Quick search English keywords
Search
Advanced search
Filter
Country/Region
Topic
Document Type
Document Category
Date
Translation Status
All other filters
Reset Filters
Last Updates
2,000
Total (3252)
Comparison Tables (0)
Regulatory Intelligence Report (44)
15
Support

View all
- クリックするとCortellis Regulatory Intelligence内の全ての収録文書のリストを表示します。
- リスト表示後、フィルタ機能で必要な文書に絞り込むことも可能です。

Quick Search
- Quick Searchは収録文書のタイトル、アブストラクト、索引を対象にキーワードやフレーズで検索できるほか、フィルタで様々な条件付けをし、検索対象の文書を絞り込むことができます。

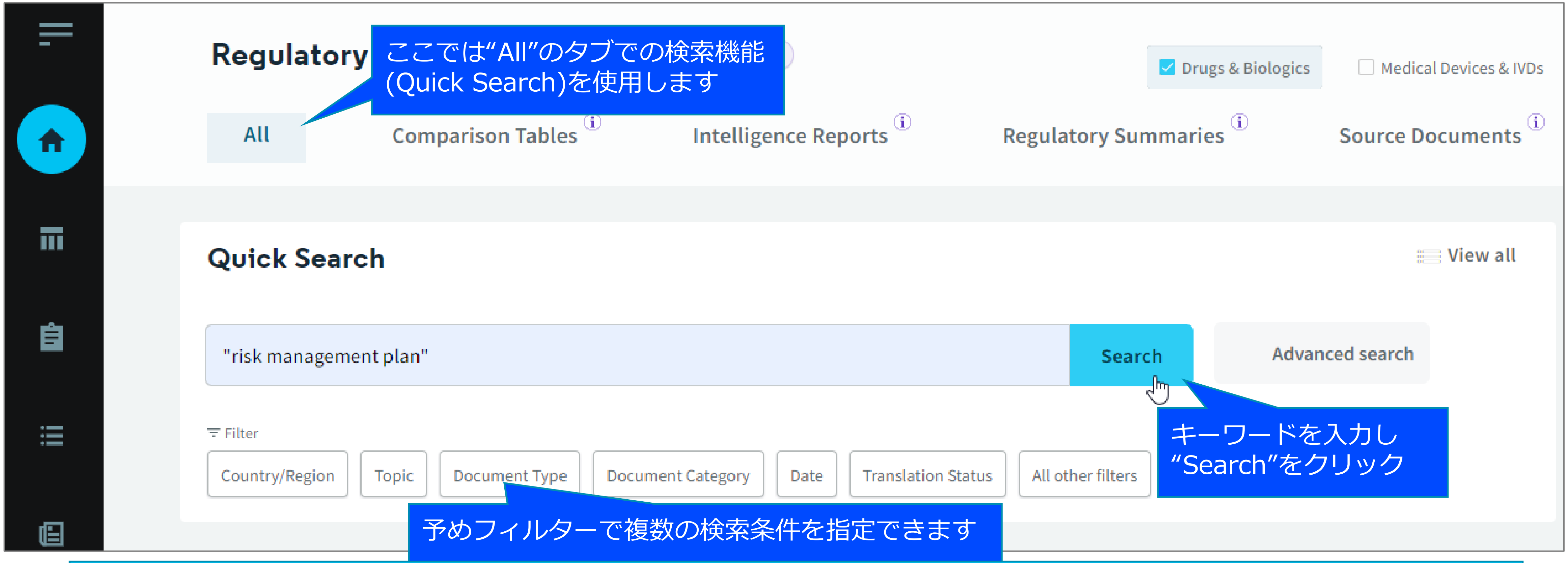
Advanced search
- 検索範囲の指定や全文検索、詳細なフィルター条件設定など、Quick Searchより細やかな検索に対応します。

2.　規制情報の収集・分析を効率的に進めるには？

- 各国規制文書の検索のコツ
- 規制情報の収集を各国の規制情報担当者がサポートする”Ask the Expert”

検索を開始するには

検索ボックスに任意のキーワードを入力してSearchをクリック


Regulatory
☑ Drugs & Biologics
☐ Medical Devices & IVDs
All
Comparison Tables
Intelligence Reports
Regulatory Summaries
Source Documents
Quick Search
View all
"risk management plan"
Search
Advanced search
Filter
Country/Region
Topic
Document Type
Document Category
Date
Translation Status
All other filters

ここでは“All”のタブでの検索機能(Quick Search)を使用します

キーワードを入力し“Search”をクリック

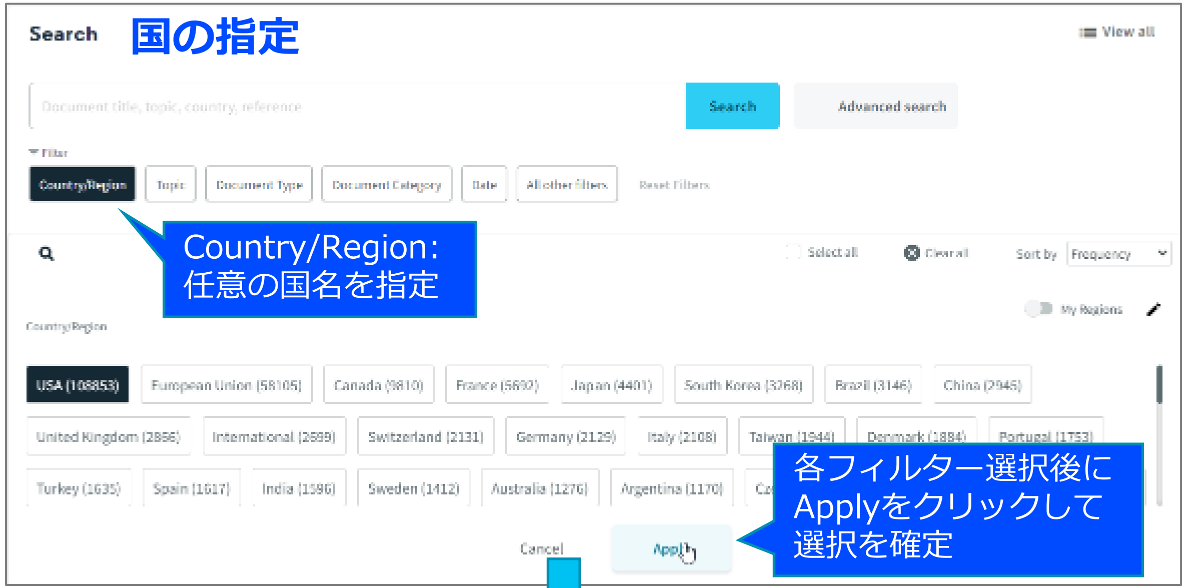
予めフィルターで複数の検索条件を指定できます

検索Tips

- “Quick Search”では、検索ワードがタイトルやアブストラクトに含まれる文書が検索結果にリストアップされます。検索語と特に関連性が高い文書を効率的にピックアップできます。
- 検索ワードを入力せずに、フィルターだけを指定して“Search”をクリックすると、フィルター条件に合致する文書を全て抽出できます。キーワードを指定せずに、特定の国や、特定のTopicの文書を網羅的に探せます。

ガイドライン検索のフィルター例

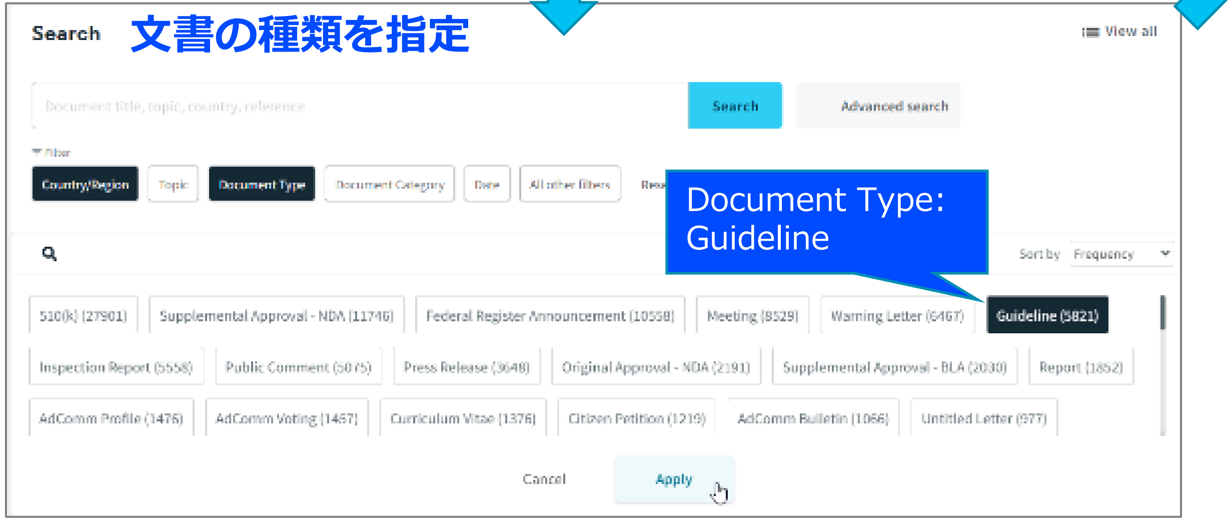
画面の例ではキーワードを指定していません


Search
View all
Document title, topic, country, reference
Search
Advanced search
Filter
Country/Region
Topic
Document Type
Document Category
Date
All other filters
Reset Filters
Select all
Clear all
Sort by
Frequency
My Regions
Country/Region
USA (108853)
European Union (58105)
Canada (9810)
France (5692)
Japan (4401)
South Korea (3268)
Brazil (3146)
China (2945)
United Kingdom (2856)
International (2699)
Switzerland (2131)
Germany (2129)
Italy (2108)
Taiwan (1944)
Denmark (1884)
Portugal (1753)
Turkey (1635)
Spain (1617)
India (1596)
Sweden (1412)
Australia (1276)
Argentina (1170)
Cancel
Apply

国の指定

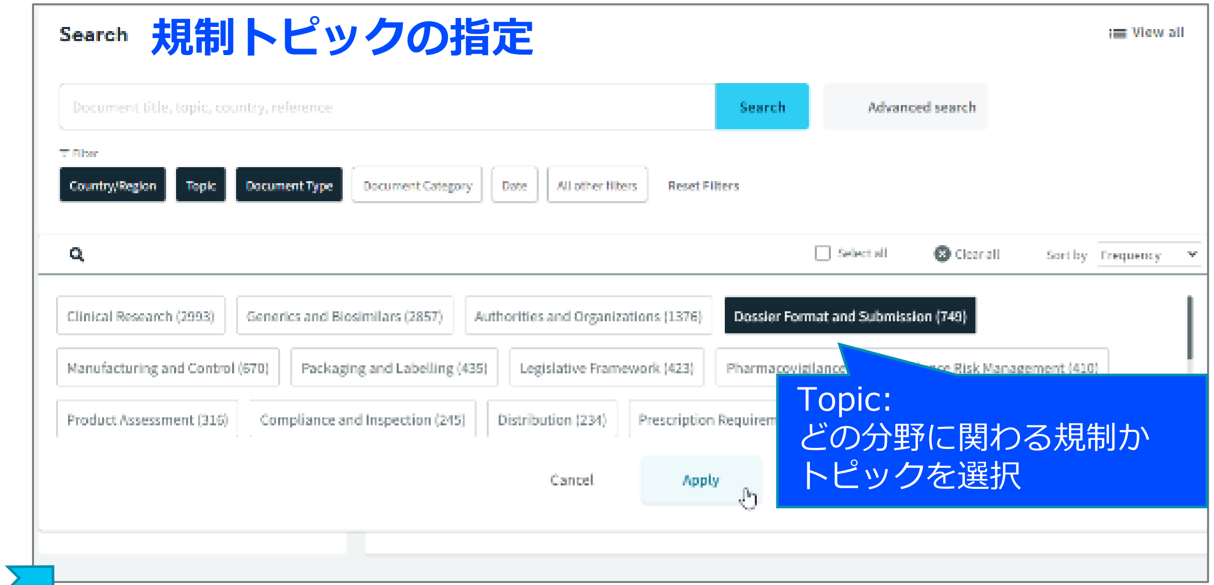
Country/Region:
任意の国名を指定

各フィルター選択後に
Applyをクリックして
選択を確定


Search
View all
Document title, topic, country, reference
Search
Advanced search
Filter
Country/Region
Topic
Document Type
Document Category
Date
All other filters
Sort by
Frequency
510(k) (27901)
Supplemental Approval - NDA (11746)
Federal Register Announcement (10558)
Meeting (8529)
Warning Letter (6467)
Guideline (5821)
Inspection Report (5558)
Public Comment (5075)
Press Release (3648)
Original Approval - NDA (2191)
Supplemental Approval - BLA (2030)
Report (1852)
AdComm Profile (1476)
AdComm Voting (1457)
Curriculum Vitae (1376)
Citizen Petition (1219)
AdComm Bulletin (1066)
Untitled Letter (977)
Cancel
Apply

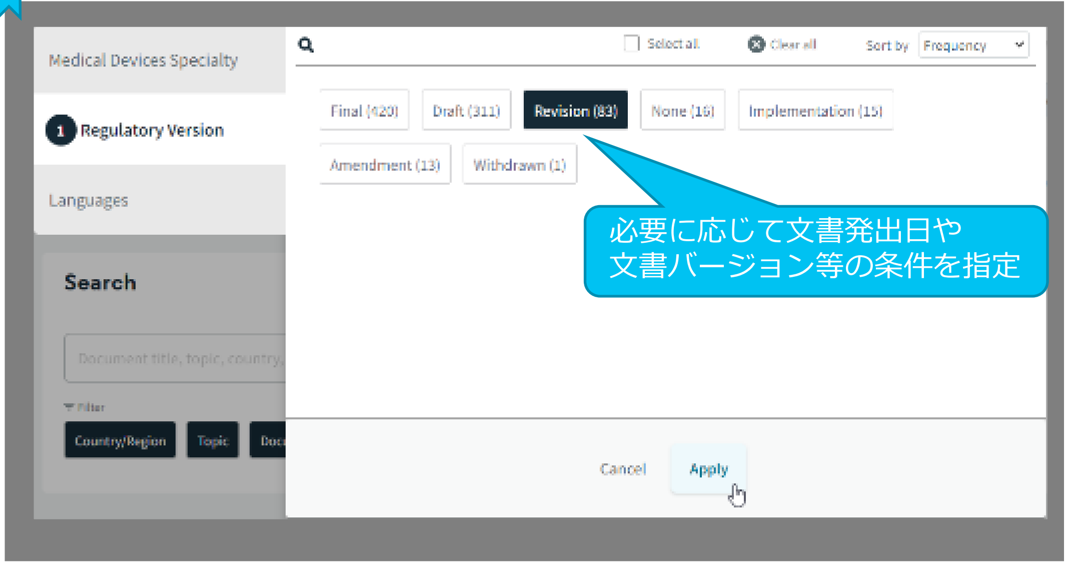
文書の種類を指定

Document Type:
Guideline


Search
View all
Document title, topic, country, reference
Search
Advanced search
Filter
Country/Region
Topic
Document Type
Document Category
Date
All other filters
Reset Filters
Select all
Clear all
Sort by
Frequency
Clinical Research (2993)
Generics and Biosimilars (2857)
Authorities and Organizations (1376)
Dossier Format and Submission (749)
Manufacturing and Control (670)
Packaging and Labelling (435)
Legislative Framework (423)
Pharmacovigilance
Risk Management (410)
Product Assessment (316)
Compliance and Inspection (245)
Distribution (234)
Prescription Requirem
Cancel
Apply

規制トピックの指定

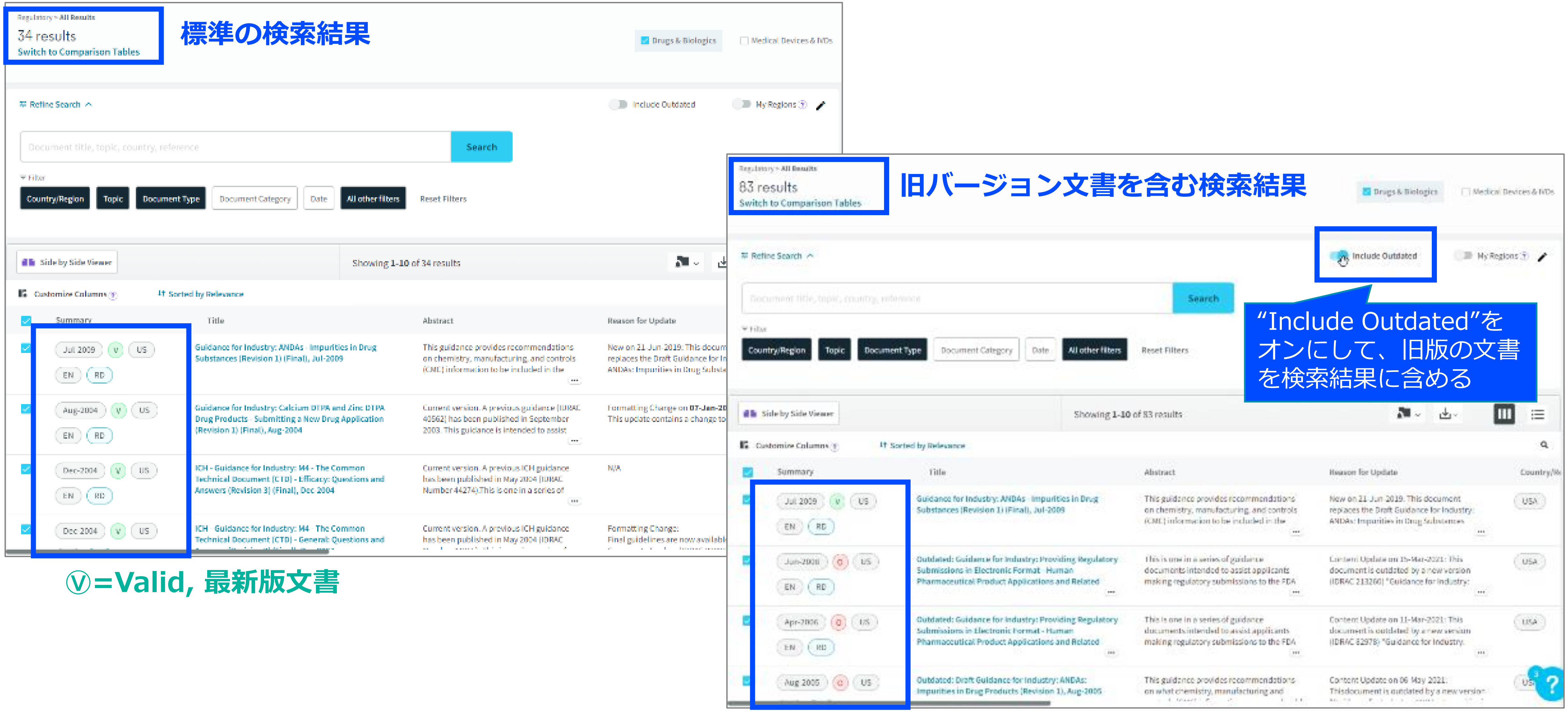
Topic:
どの分野に関わる規制か
トピックを選択


Medical Devices Specialty
1 Regulatory Version
Languages
Search
Document title, topic, country,
Filter
Country/Region
Topic
Select all
Clear all
Sort by
Frequency
Final (420)
Draft (311)
Revision (83)
None (16)
Implementation (15)
Amendment (13)
Withdrawn (1)
Cancel
Apply

必要に応じて文書発出日や
文書バージョン等の条件を指定

検索結果画面

標準表示は最新版（Valid）文書のみをリストアップ、旧バージョンを結果に追加表示可能



標準の検索結果

Regulatory > All Results
34 results
Switch to Comparison Tables

☑ Drugs & Biologics ☐ Medical Devices & IVDs

Refine Search
Include Outdated
My Regions
Document title, topic, country, reference
Search
Filter
Country/Region
Topic
Document Type
Document Category
Date
All other filters
Reset Filters
Side by Side Viewer
Customize Columns
Sorted by Relevance

Showing 1-10 of 34 results

Summary	Title	Abstract	Reason for Update
Jul 2009 V US EN RD	Guidance for Industry: ANDAs - Impurities in Drug Substances (Revision 1) (Final), Jul-2009	This guidance provides recommendations on chemistry, manufacturing, and controls (CMC) information to be included in the …	New on 21 Jun 2019. This docum replaces the Draft Guidance for In ANDAs: Impurities in Drug Substa
Aug-2004 V US EN RD	Guidance for Industry: Calcium DTPA and Zinc DTPA Drug Products - Submitting a New Drug Application (Revision 1) (Final), Aug-2004	Current version. A previous guidance (IDRAC 40562) has been published in September 2003. This guidance is intended to assist …	Formatting Change on 07-Jan-20 This update contains a change to
Dec-2004 V US EN RD	ICH - Guidance for Industry: M4 - The Common Technical Document (CTD) - Efficacy: Questions and Answers (Revision 3) (Final), Dec 2004	Current version. A previous ICH guidance has been published in May 2004 (IDRAC Number 44274).This is one in a series of …	N/A
Dec 2004 V US	ICH - Guidance for Industry: M4 - The Common Technical Document (CTD) - General: Questions and	Current version. A previous ICH guidance has been published in May 2004 (IDRAC	Formatting Change: Final guidelines are now availabl

ⓥ=Valid, 最新版文書

旧バージョン文書を含む検索結果

Regulatory > All Results
83 results
Switch to Comparison Tables

☑ Drugs & Biologics ☐ Medical Devices & IVDs

Refine Search
Include Outdated
My Regions
Document title, topic, country, reference
Search
Filter
Country/Region
Topic
Document Type
Document Category
Date
All other filters
Reset Filters
Side by Side Viewer
Customize Columns
Sorted by Relevance

“Include Outdated”をオンにして、旧版の文書を検索結果に含める

Showing 1-10 of 83 results

Summary	Title	Abstract	Reason for Update	Country/Re
Jul 2009 V US EN RD	Guidance for Industry: ANDAs - Impurities in Drug Substances (Revision 1) (Final), Jul-2009	This guidance provides recommendations on chemistry, manufacturing, and controls (CMC) information to be included in the …	New on 21 Jun 2019. This document replaces the Draft Guidance for Industry: ANDAs: Impurities in Drug Substances …	USA
Jun-2008 O US EN RD	Outdated: Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Human Pharmaceutical Product Applications and Related …	This is one in a series of guidance documents intended to assist applicants making regulatory submissions to the FDA …	Content Update on 15-Mar-2021: This document is outdated by a new version (IDRAC 213260) "Guidance for Industry: …	USA
Apr-2006 O US EN RD	Outdated: Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Human Pharmaceutical Product Applications and Related …	This is one in a series of guidance documents intended to assist applicants making regulatory submissions to the FDA …	Content Update on 11-Mar-2021: This document is outdated by a new version (IDRAC 82978) "Guidance for Industry. …	USA
Aug 2005 O US	Outdated: Draft Guidance for Industry: ANDAs: Impurities in Drug Products (Revision 1), Aug-2005	This guidance provides recommendations on what chemistry, manufacturing and	Content Update on 06 May 2021: This document is outdated by a new version	US

ⓞ=Outdated, 旧バージョン文書

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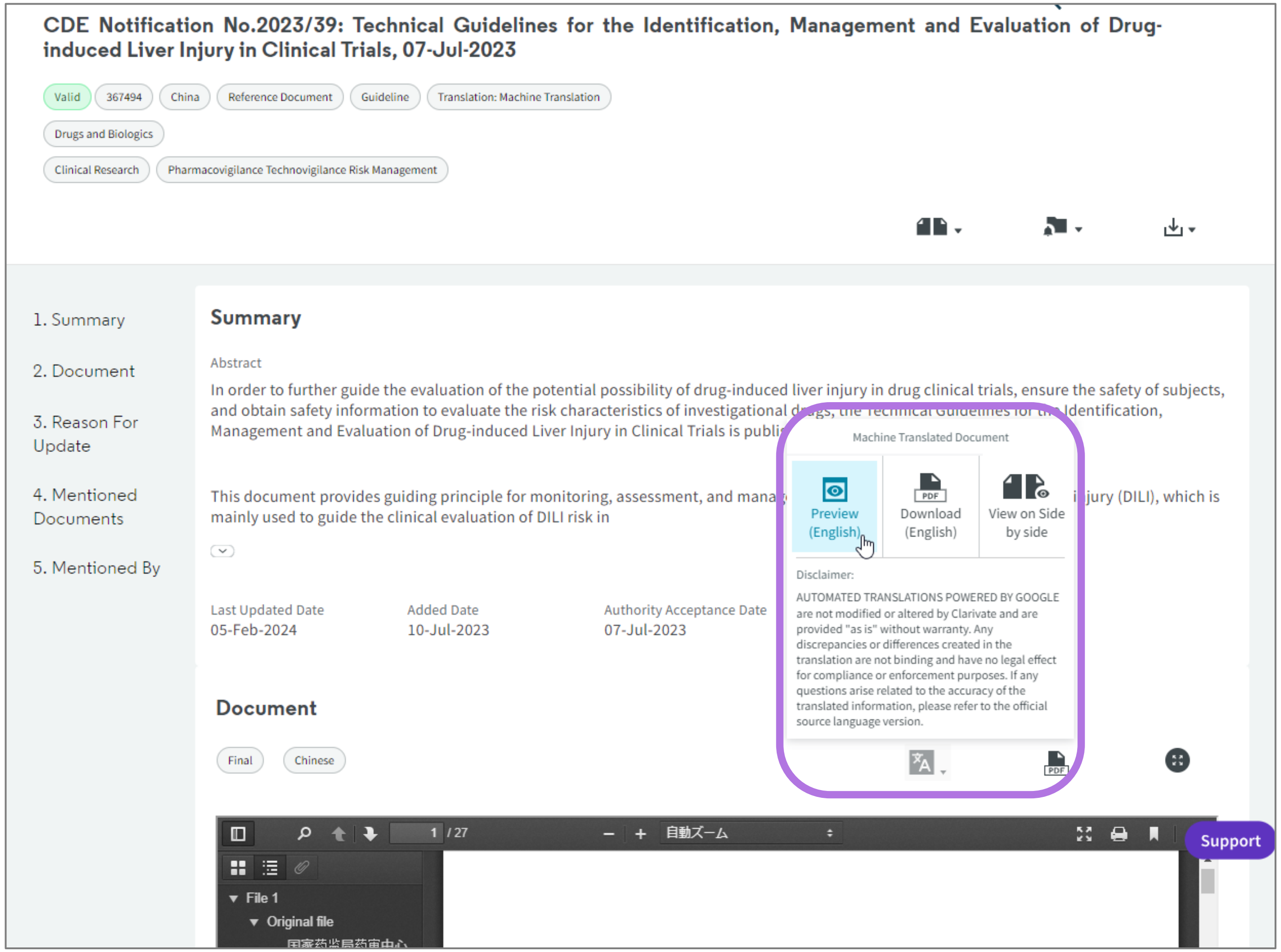
全収録国を対象とした規制文書の機械翻訳（英語）



CDE Notification No.2023/39: Technical Guidelines for the Identification, Management and Evaluation of Drug-induced Liver Injury in Clinical Trials, 07-Jul-2023

Valid | 367494 | China | Reference Document | Guideline | Translation: Machine Translation

Drugs and Biologics

Clinical Research | Pharmacovigilance Technovigilance Risk Management

1. Summary
2. Document
3. Reason For Update
4. Mentioned Documents
5. Mentioned By

Summary

Abstract

In order to further guide the evaluation of the potential possibility of drug-induced liver injury in drug clinical trials, ensure the safety of subjects, and obtain safety information to evaluate the risk characteristics of investigational drugs, the Technical Guidelines for the Identification, Management and Evaluation of Drug-induced Liver Injury in Clinical Trials is publi

This document provides guiding principle for monitoring, assessment, and mana jury (DILI), which is mainly used to guide the clinical evaluation of DILI risk in

Last Updated Date	Added Date	Authority Acceptance Date
05-Feb-2024	10-Jul-2023	07-Jul-2023

Document

Final | Chinese

Machine Translated Document
Preview (English)
Download (English)
View on Side by side
1 / 27
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File 1
Original file
Support

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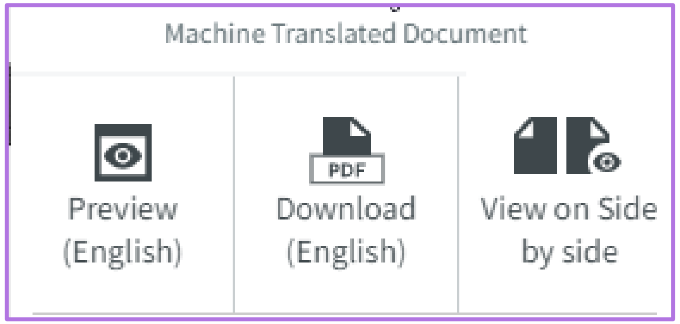
機械翻訳アイコンをクリックすると、翻訳済みの文書を表示またはダウンロードするためのメニューが表示されます。



Machine Translated Document
Preview (English)
Download (English)
View on Side by side

- 収録済み文書も順次遡及的に機械翻訳を追加しています（Valid ＝最新版文書のみ対象）
- 従来よりマニュアルでの英語翻訳を提供していた以下の国については引き続きマニュアル翻訳もご提供いたします。
  - Drugs and Biologics: China, South Korea, Taiwan, Japan, Brazil, Mexico, Israel, Russia

検索Tips –フィルターの紹介

フィルター名称	フィルター項目例	概要説明
Country/Region	USA, China, European Union, Internationalなど	• 検索対象にしたい国や地域の指定ができます
Topic	Clinical research, Dossier format and submission, Product Assessment, Manufacturing and control, GXP, Orphan Productsなど	• 各規制文書/レポートの内容が関連するトピック項目のインデックスを編集部にて付与しており、大まかな絞り込みに活用できます
Document Type	Law, Guideline, Notification, EPAR, Meeting, Inspection Report, Warning Letterなど	• 各規制文書/レポートの内容が関連する文書の種類を指定できます • 各国発出文書の種類についてはRegulatory Intelligence Report内の”Reference Document Inventory”でも情報が得られます
Document Category	Reference Document Regulatory Summary Regulatory Intelligence Report	• Reference Document（各国当局の公式文書） • Regulatory Summary（規制の解説文書） • Regulatory Intelligence Report（ガイドラインのまとめや承認情報レポートなど）
Date	Authority Acceptance Date, Source Publication Date, Coming into Force Date, Last Update	• 発出日等の範囲指定で文書を絞り込むことができます • Authority Acceptance Date: 当局における文書の可決/採択日 • Source Publication Date：当局ウェブサイトでの公開日 • Coming into Force Date：規制の発効予定日 • Last Update：データベース上の最終更新日（新規掲載、翻訳追加、アブストラクト記載変更等なんらかの更新を行った日付）

検索Tips –フィルターの紹介

フィルター名称	フィルター項目例	概要説明
Translation Status	Official, Unofficial, Internal, In Progress	• Official: 規制当局によって公式版と明示された英語版文書 • Unofficial: 公式版であることが明示されていない英語版（当局が公開している英語文書も含む） • Internal: クラリベイトによる英語翻訳 • In Progress: クラリベイトの翻訳中文書（完了予定日を確認可能）
Company	製薬企業、医療機器メーカー等	• Companyの索引が付与されたDocument Typeについて、企業名での絞り込みが可能です。Company索引付与対象は以下の文書です。 • 医薬品のProduct Approval文書 • 医療機器のProduct Approval文書 • Pediatric Decision / Written Request • Warning Letter
Regulatory Version	Final, Revision, Draft等	• 規制文書のバージョン（当局によって明らかにされているもの）
Languages	English, Russian, Chinese等	• 規制文書の言語による絞り込みが可能
Dosage Form **(Drugs & Biologicsモジュールのみ)**	Tablet, Powder, Gel, Spray, Solution etc.	• 医薬品のProduct Approval文書を対象に、剤型での絞り込みが可能(Drugs & Biologicsモジュールのみ)

薬事規制業務に必要な実用的なインサイト

Cortellis Regulatory Intelligenceの付加価値コンテンツ

Source Documents

- 世界各国の規制当局・機関の公式文書
- 最新および過去バージョンを蓄積（バージョン管理情報付与）
- 全ての規制文書に英語のタイトル・抄録・更新理由等付加
- 現地語文書に機械翻訳を付与
- さらに一部の国は専門家による全文英訳を追加
- Medical Devices & IVDs: 16カ国
  China, South Korea, Taiwan, Japan, Brazil, Mexico, Israel, Russia, Argentina, Austria, France, Germany, Italy, Spain, Switzerland, Turkey

Regulatory Summaries

- 薬事専門家による各国の規制の枠組み・プロセスの英語解説文
- 標準化されたフォーマット
- 主要な規制文書をリスト
- 規制変更により随時更新

Regulatory Intelligence Reports

- 様々な重要トピックについて実務に役立つ規制分析レポート
  - 規制変更追跡
  - 競合品承認情報
  - FDA査察情報　等

Global Regulatory Comparisons

- 重要トピックに関する世界各国の規制比較表
- 規制の共通点・相違点を簡単に把握
- 主要な規制文書へのリンクで簡単に詳細を確認可能
- 随時更新

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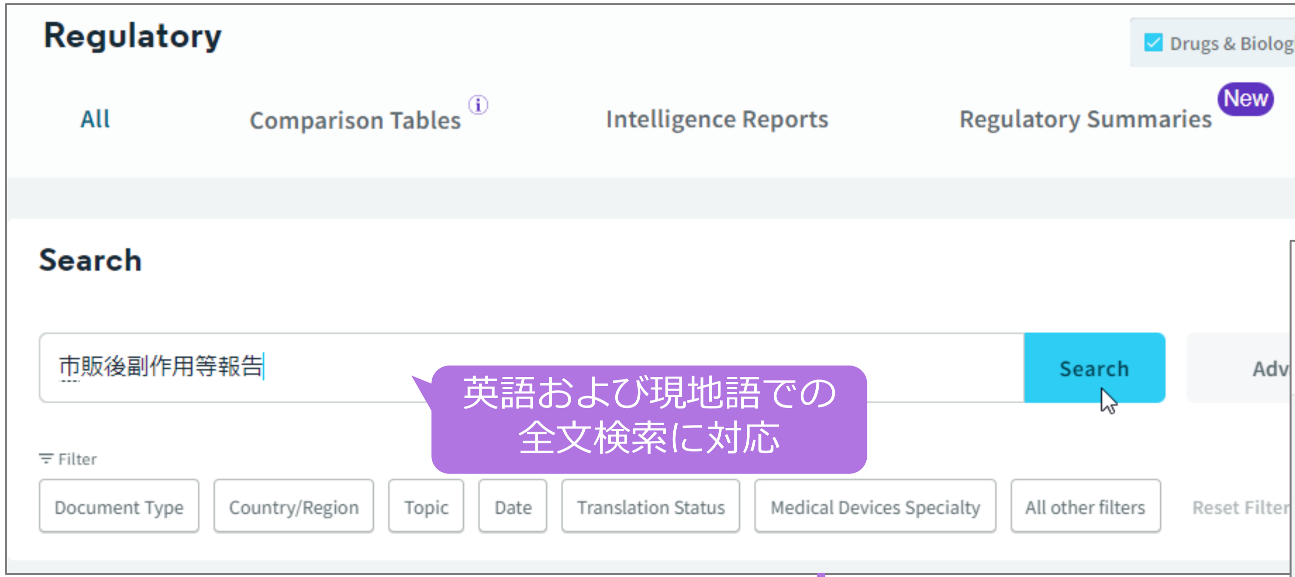
Source Documents(現地規制文書)検索の強化

現地語を含む全文検索に対応



Regulatory

☑ Drugs & Biologics ☐ Medical Devices & IVDs

All | Comparison Tables | Intelligence Reports | Regulatory Summaries New | Source Documents Updated

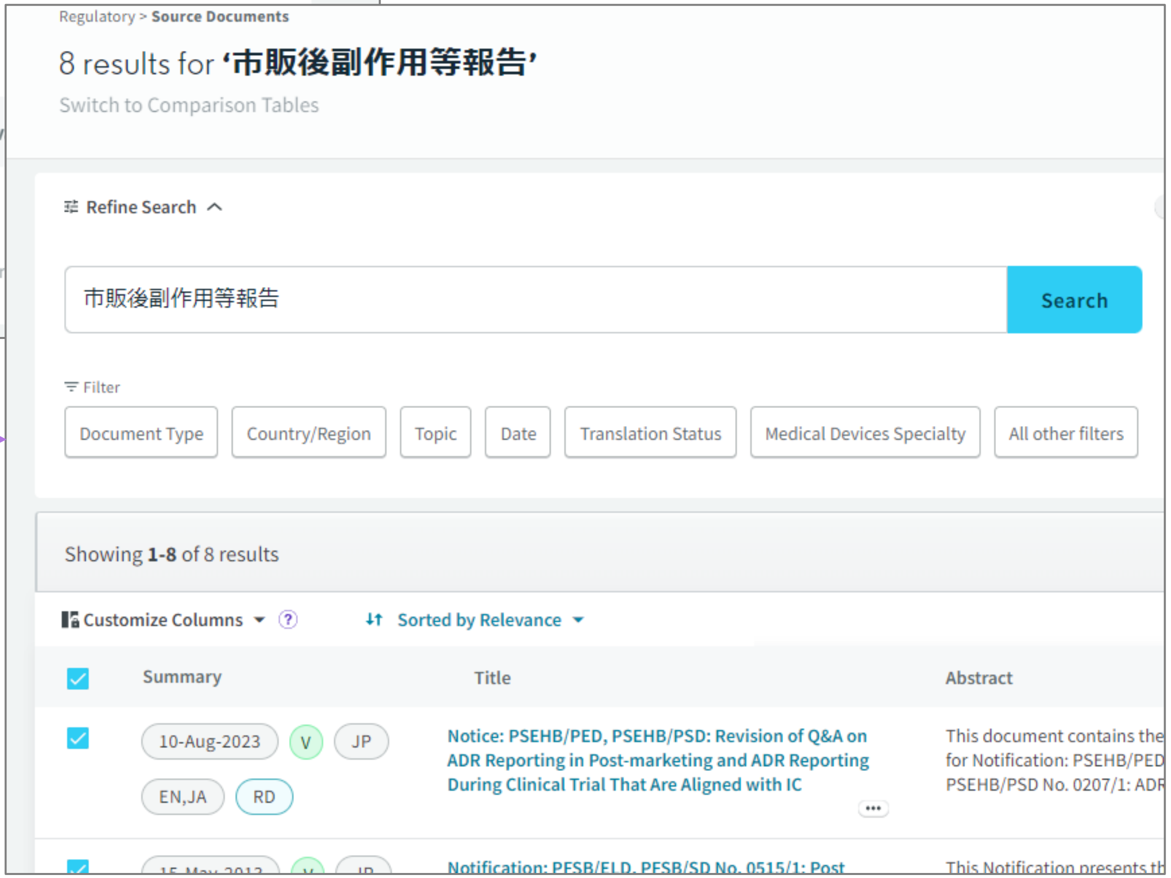
Search

市販後副作用等報告 | Search | Adv

Filter: Document Type | Country/Region | Topic | Date | Translation Status | Medical Devices Specialty | All other filters | Reset Filter

“Source Documents”タブに切り替えて検索を実行

英語および現地語での全文検索に対応



Regulatory > **Source Documents**

8 results for **‘市販後副作用等報告’**

Switch to Comparison Tables

Refine Search

市販後副作用等報告 | Search

Filter: Document Type | Country/Region | Topic | Date | Translation Status | Medical Devices Specialty | All other filters

Showing **1-8** of 8 results

Customize Columns | Sorted by Relevance

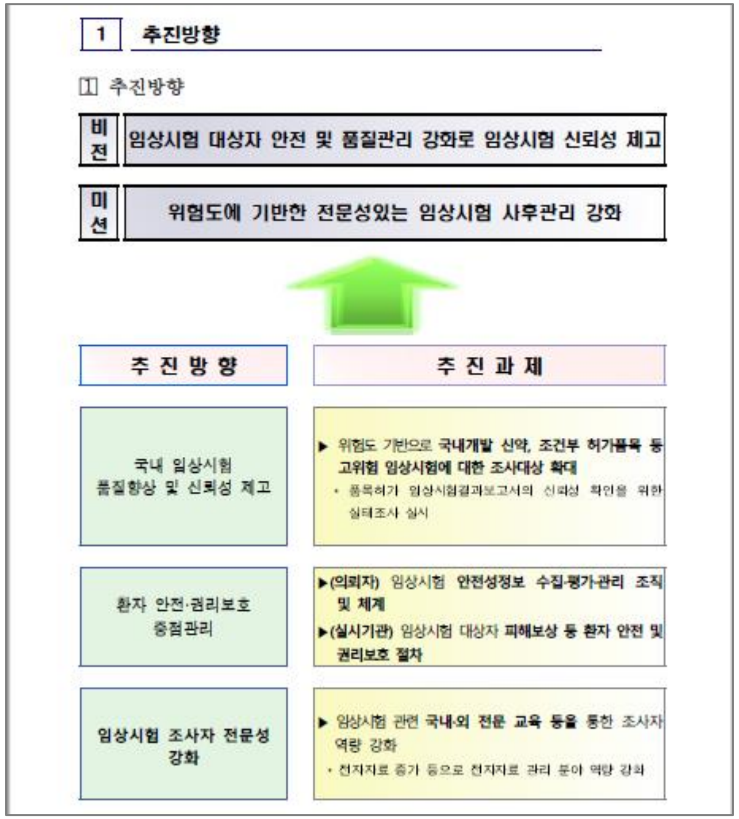
☑	Summary	Title	Abstract
☑	10-Aug-2023 V JP EN,JA RD	Notice: PSEHB/PED, PSEHB/PSD: Revision of Q&A on ADR Reporting in Post-marketing and ADR Reporting During Clinical Trial That Are Aligned with IC	This document contains the for Notification: PSEHB/PED PSEHB/PSD No. 0207/1: ADR
☑		Notification: PFSB/ELD, PFSB/SD No. 0515/1: Post	

- “Source Documents”のタブ内で検索を実行すると、検索対象文書が自動的に**Source Documentのみに限定**されます。
- “All”タブの“Quick Search”とは異なり、文書のタイトル、アブストラクトに加え、**PDFの文書全文も検索対**象になります。
- 検索範囲が広がって網羅的な調査ができますが、検索ワードとの関連性が低い文書も検索結果に含まれる可能性が高まります。
- Source Documentsタブ内の検索では、検索ワードとして**現地語も使用可能**です。

コンテンツ例

規制文書の英語翻訳入手

- **Source Documents - 各国の規制の知識を持つコンサルタントによる英語翻訳**を入手
- Drugs & Biologics英訳対象国：China, South Korea, Taiwan, Japan, Brazil, Mexico, Israel, Russia
- Medical Devices & IVDs英訳対象国：上記8か国に加えArgentina, Austria, France, Germany, Italy, Spain, Switzerland, Turkey
- 2023年12月以降、上記の国を含む全収録国の規制文書（英語以外の文書）が機械翻訳の対象になりました。上記の国は機械翻訳に加え、従来通りのマニュアル翻訳も継続してご提供します。

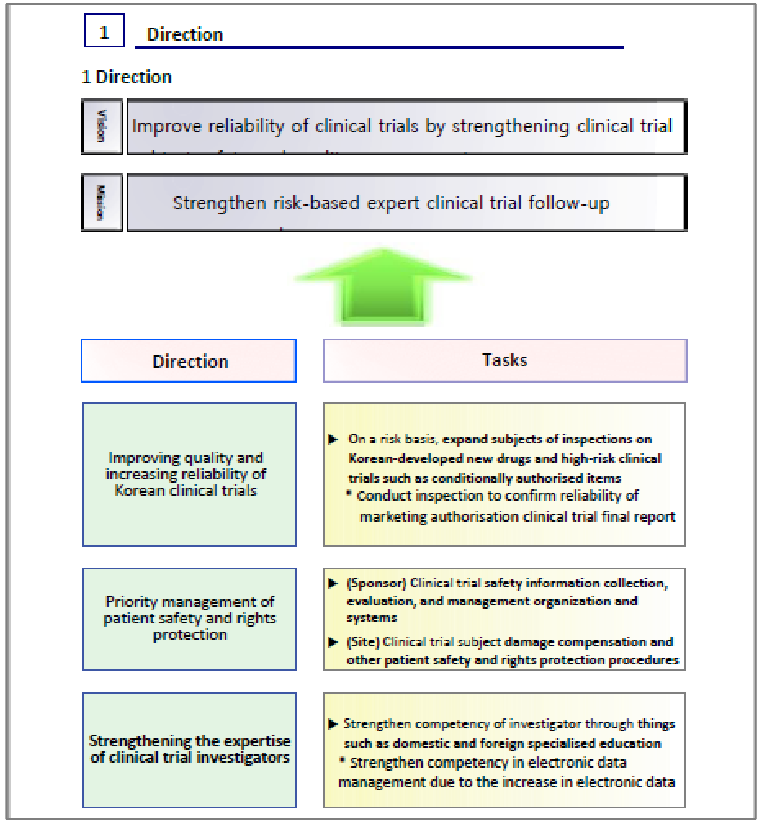


1 추진방향

□1 추진방향

비전	임상시험 대상자 안전 및 품질관리 강화로 임상시험 신뢰성 제고
미션	위험도에 기반한 전문성있는 임상시험 사후관리 강화

추 진 방 향	추 진 과 제
국내 임상시험 품질향상 및 신뢰성 제고	▶ 위험도 기반으로 국내개발 신약, 조건부 허가품목 등 고위험 임상시험에 대한 조사대상 확대 · 품목허가 임상시험결과보고서의 신뢰성 확인을 위한 실태조사 실시
환자 안전·권리보호 중점관리	▶(의뢰자) 임상시험 안전성정보 수집·평가·관리 조직 및 체계 ▶(실시기관) 임상시험 대상자 피해보상 등 환자 안전 및 권리보호 절차
임상시험 조사자 전문성 강화	▶ 임상시험 관련 국내·외 전문 교육 등을 통한 조사자 역량 강화 · 전자자료 증가 등으로 전자자료 관리 분야 역량 강화



1 Direction

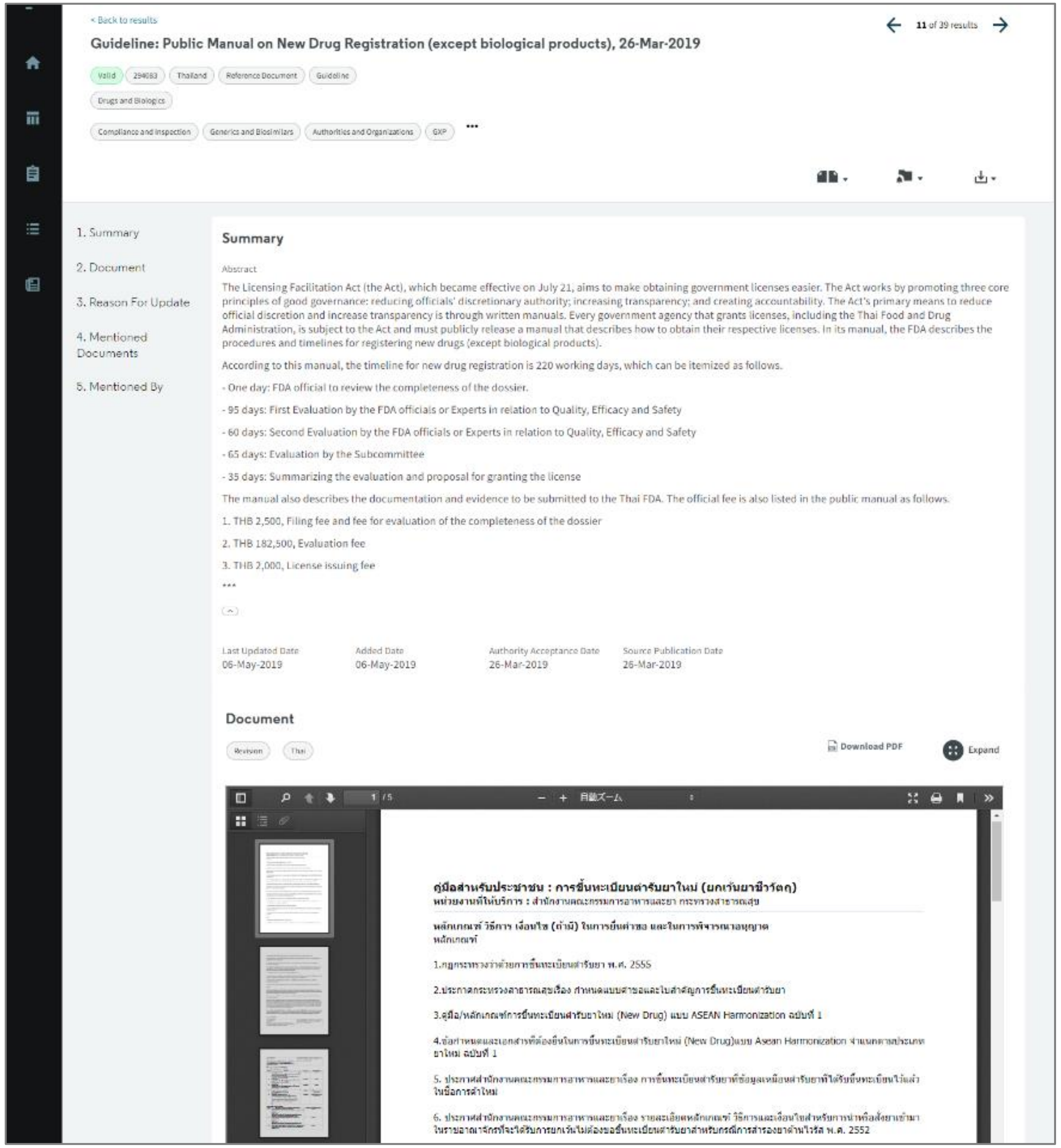
1 Direction

Vision	Improve reliability of clinical trials by strengthening clinical trial
Mission	Strengthen risk-based expert clinical trial follow-up

Direction	Tasks
Improving quality and increasing reliability of Korean clinical trials	▶ On a risk basis, expand subjects of inspections on Korean-developed new drugs and high-risk clinical trials such as conditionally authorised items * Conduct inspection to confirm reliability of marketing authorisation clinical trial final report
Priority management of patient safety and rights protection	▶ (Sponsor) Clinical trial safety information collection, evaluation, and management organization and systems ▶ (Site) Clinical trial subject damage compensation and other patient safety and rights protection procedures
Strengthening the expertise of clinical trial investigators	▶ Strengthen competency of investigator through things such as domestic and foreign specialised education * Strengthen competency in electronic data management due to the increase in electronic data

Source Documents（規制当局の文書）の特徴

英語のタイトル	全規制文書にタイトルの英語訳を付与。
文書のアブストラクト	全収録文書に当該文書で扱われているトピック概要や、文書のサマリ等を付与。
発出日や施行予定日の情報	規制文書の日付、当局ウェブサイトでの公開日、規制の施行日。
規制文書のバージョン情報	最新版/現地で効力を持っている文書には”Valid”, 古いバージョンの文書や既に撤廃された規制には”Outdated”のインデックスを付与。
規制文書の英語翻訳	全ての英語以外の文書にCRI収録時点から英語の機械翻訳を提供。 China, South Korea, Taiwan, Japan, Brazil, Mexico, Israel, Russiaの8か国は引き続きマニュアル英語翻訳も対応。
関連文書へのリンク	バージョン違いの文書や、内容に関連性のある文書等へのリンク付与。


< Back to results
11 of 39 results
Valid
294083
Thailand
Reference Document
Guideline
Drugs and Biologics
Compliance and Inspection
Generics and Biosimilars
Authorities and Organizations
GXP
1. Summary
2. Document
3. Reason For Update
4. Mentioned Documents
5. Mentioned By
Revision
Thai
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1 / 5
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Guideline: Public Manual on New Drug Registration (except biological products), 26-Mar-2019

Summary

Abstract

The Licensing Facilitation Act (the Act), which became effective on July 21, aims to make obtaining government licenses easier. The Act works by promoting three core principles of good governance: reducing officials' discretionary authority; increasing transparency; and creating accountability. The Act's primary means to reduce official discretion and increase transparency is through written manuals. Every government agency that grants licenses, including the Thai Food and Drug Administration, is subject to the Act and must publicly release a manual that describes how to obtain their respective licenses. In its manual, the FDA describes the procedures and timelines for registering new drugs (except biological products).

According to this manual, the timeline for new drug registration is 220 working days, which can be itemized as follows.

- One day: FDA official to review the completeness of the dossier.
- 95 days: First Evaluation by the FDA officials or Experts in relation to Quality, Efficacy and Safety
- 60 days: Second Evaluation by the FDA officials or Experts in relation to Quality, Efficacy and Safety
- 65 days: Evaluation by the Subcommittee
- 35 days: Summarizing the evaluation and proposal for granting the license

The manual also describes the documentation and evidence to be submitted to the Thai FDA. The official fee is also listed in the public manual as follows.

1. THB 2,500, Filing fee and fee for evaluation of the completeness of the dossier
2. THB 182,500, Evaluation fee
3. THB 2,000, License issuing fee

***

Last Updated Date	Added Date	Authority Acceptance Date	Source Publication Date
06-May-2019	06-May-2019	26-Mar-2019	26-Mar-2019

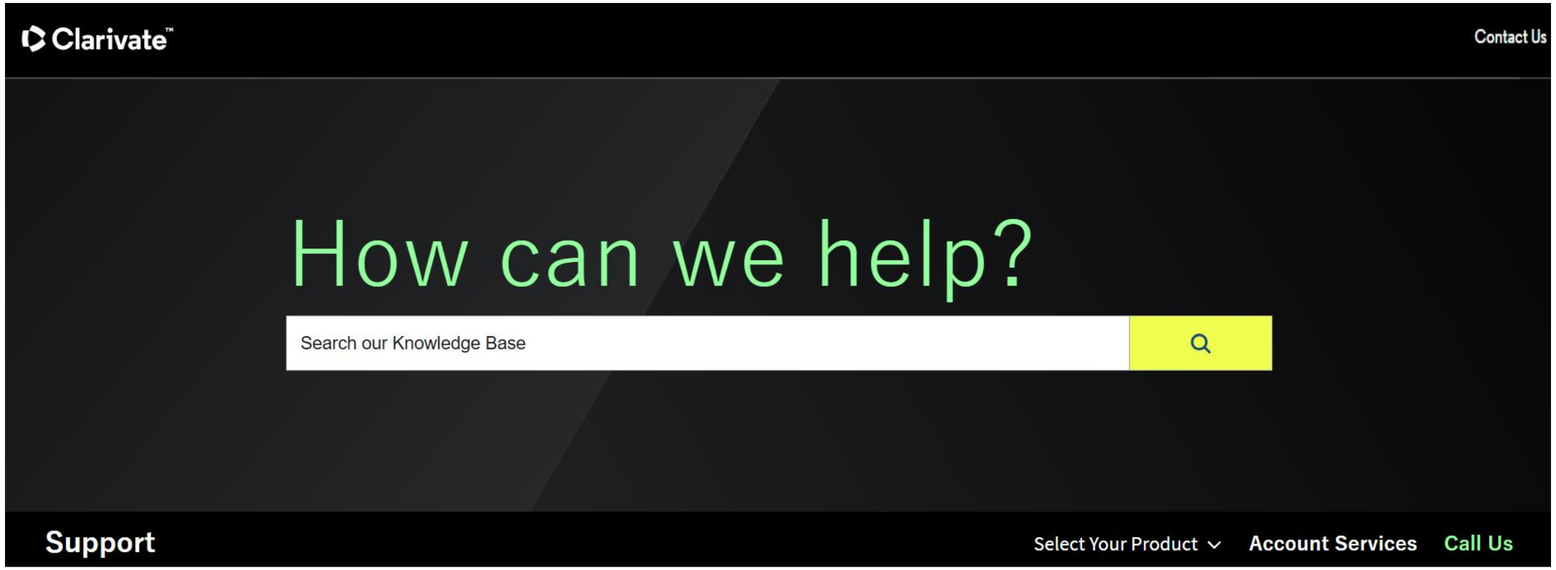
Document

規制調査のサポート

エキスパートの知見を活用

規制情報収集を各国規制情報担当者がサポートする”Ask the Expert”

- 各国規制の専門エディター、ローカルコンサルタントに規制の内容について問い合わせ可能
- カスタマーケアを通じて日本語での対応



How can we help?

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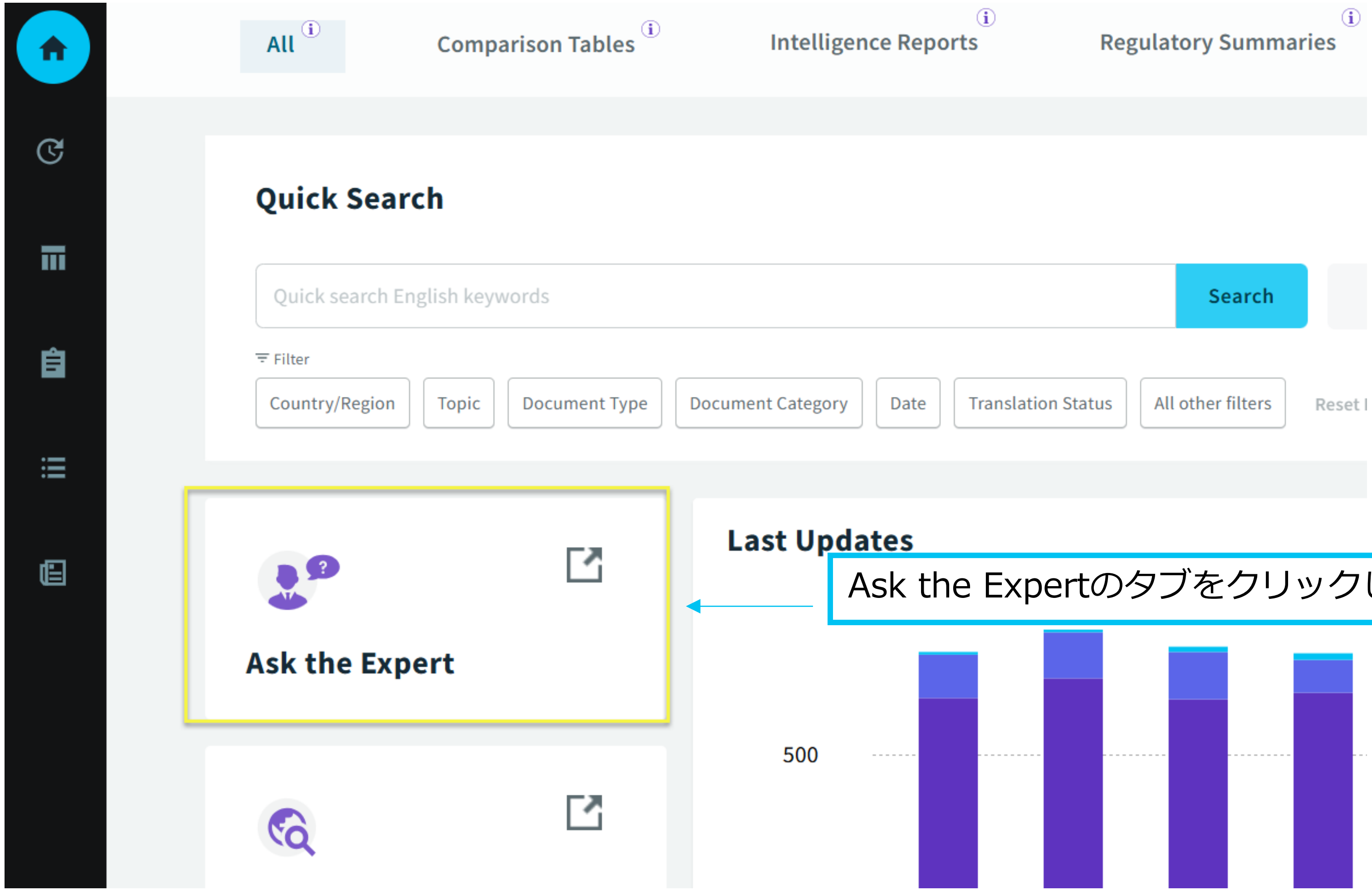
Support
Select Your Product
Account Services
Call Us

Ask a Life Sciences expert

Ask the Expertへのアクセス


All
Comparison Tables
Intelligence Reports
Regulatory Summaries
Quick Search
Quick search English keywords
Search
Filter
Country/Region
Topic
Document Type
Document Category
Date
Translation Status
All other filters
Reset
Ask the Expert
Last Updates
500

Ask the Expertのタブをクリックしトピックの一覧を開く

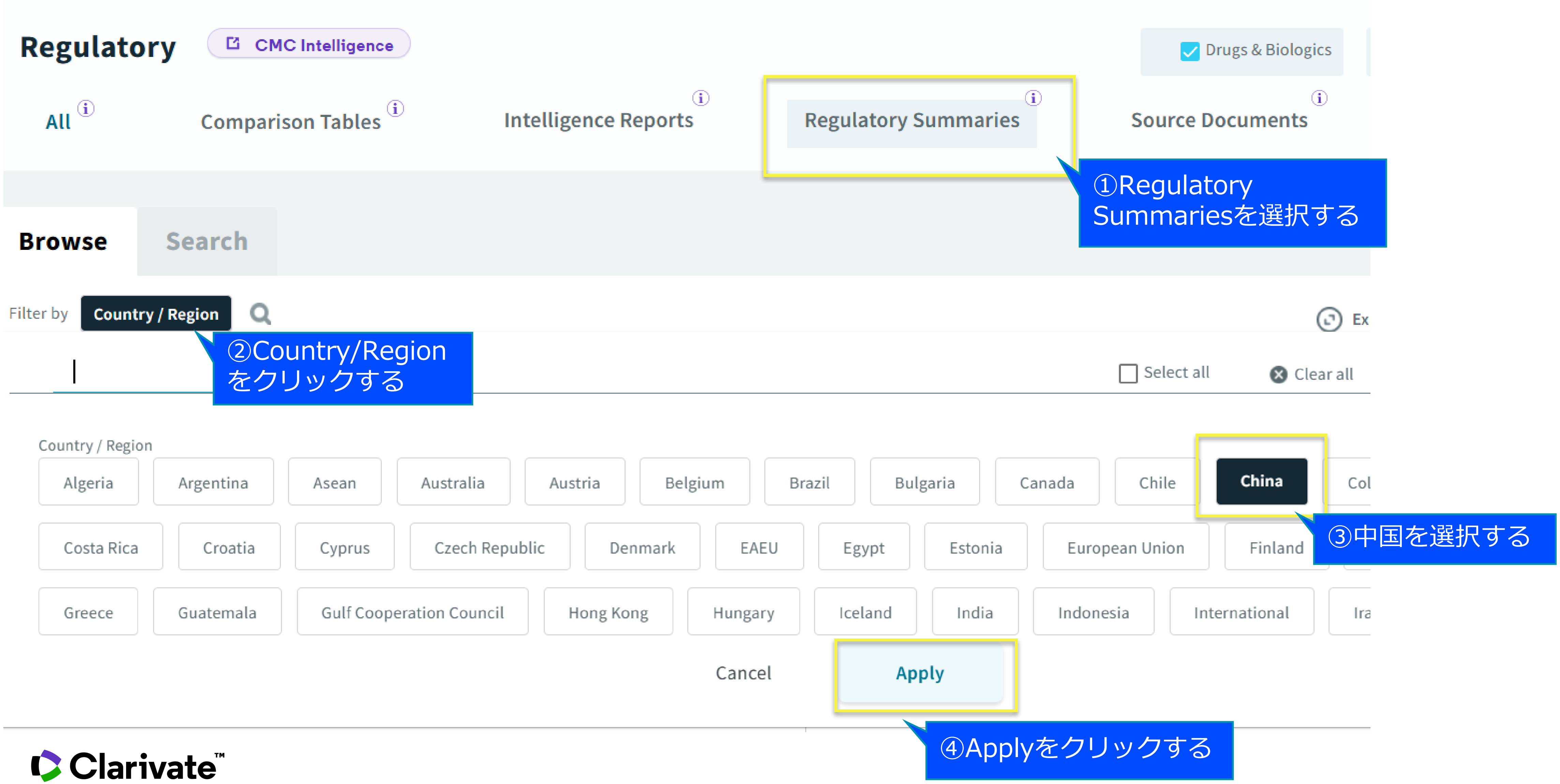
Clarivate™

3．コンプライアンス維持のために
各国規制の最新情報をモニタリングするには？

- 規制の最新アップデート情報を入手する為のCustom AlertとWeekly Alert Mail
- 規制のモニタリングに活用できるレポート例のご紹介

収録レポートやサマリへのアラート設定 (Alert on Report)

例：中国におけるCGP要件について、更新時に同僚へ自動で内容を通知する


Regulatory
CMC Intelligence
Drugs & Biologics
All
Comparison Tables
Intelligence Reports
Regulatory Summaries
Source Documents
Browse
Search
Filter by
Country / Region
Ex
Select all
Clear all
Country / Region
Algeria
Argentina
Asean
Australia
Austria
Belgium
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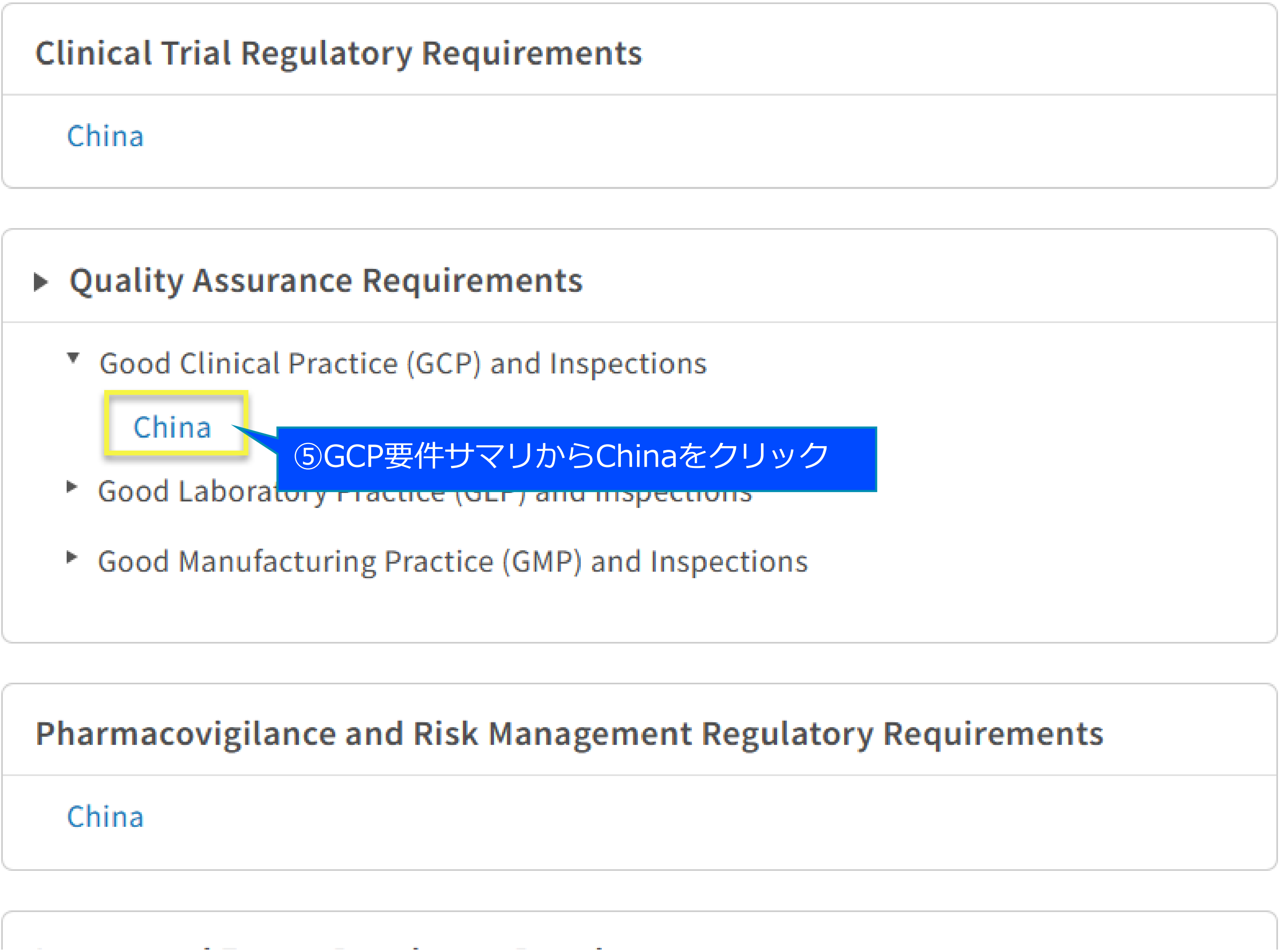
Chile
China
Col
Costa Rica
Croatia
Cyprus
Czech Republic
Denmark
EAEU
Egypt
Estonia
European Union
Finland
Greece
Guatemala
Gulf Cooperation Council
Hong Kong
Hungary
Iceland
India
Indonesia
International
Ira
Cancel
Apply

①Regulatory Summariesを選択する

②Country/Regionをクリックする

③中国を選択する

④Applyをクリックする



Clinical Trial Regulatory Requirements

China

▶ Quality Assurance Requirements

▼ Good Clinical Practice (GCP) and Inspections

China

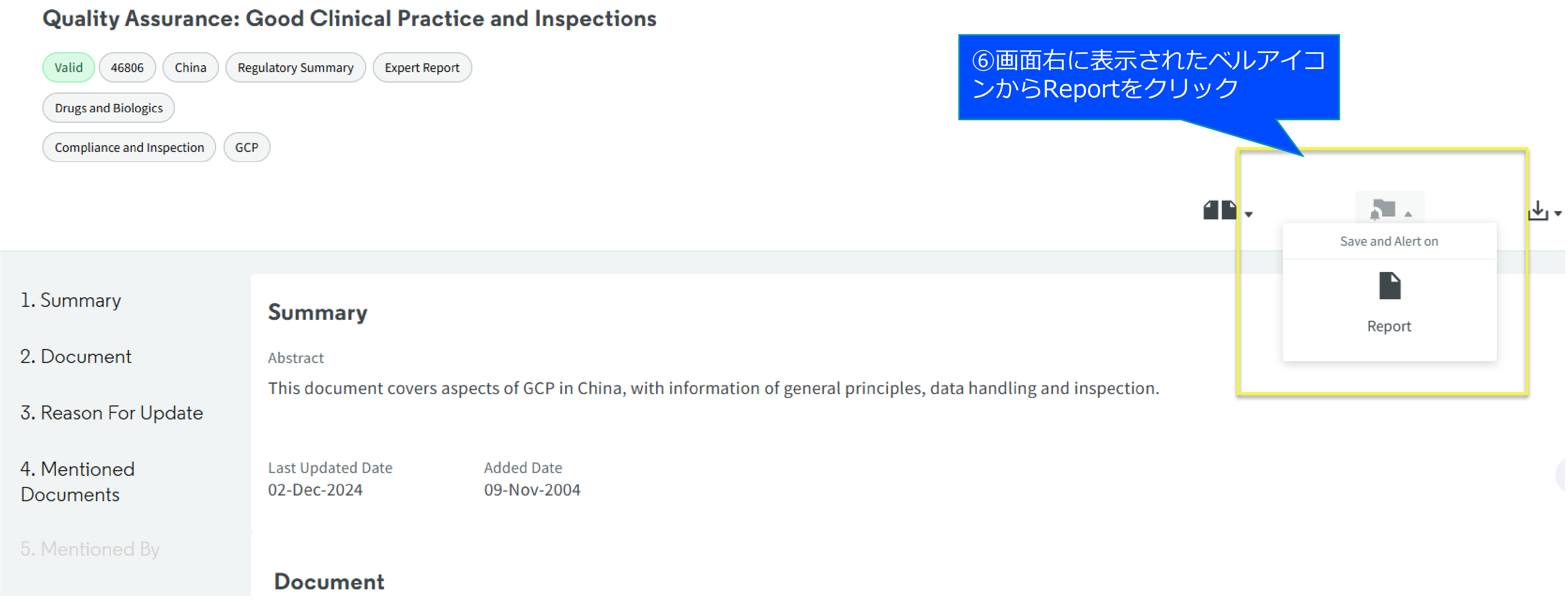
⑤GCP要件サマリからChinaをクリック

▸ Good Laboratory Practice (GLP) and Inspections

▸ Good Manufacturing Practice (GMP) and Inspections

Pharmacovigilance and Risk Management Regulatory Requirements

China



⑥画面右に表示されたベルアイコンからReportをクリック

Quality Assurance: Good Clinical Practice and Inspections

Valid
46806
China
Regulatory Summary
Expert Report
Drugs and Biologics
Compliance and Inspection
GCP
Save and Alert on
Report
1. Summary
2. Document
3. Reason For Update
4. Mentioned Documents
5. Mentioned By

Summary

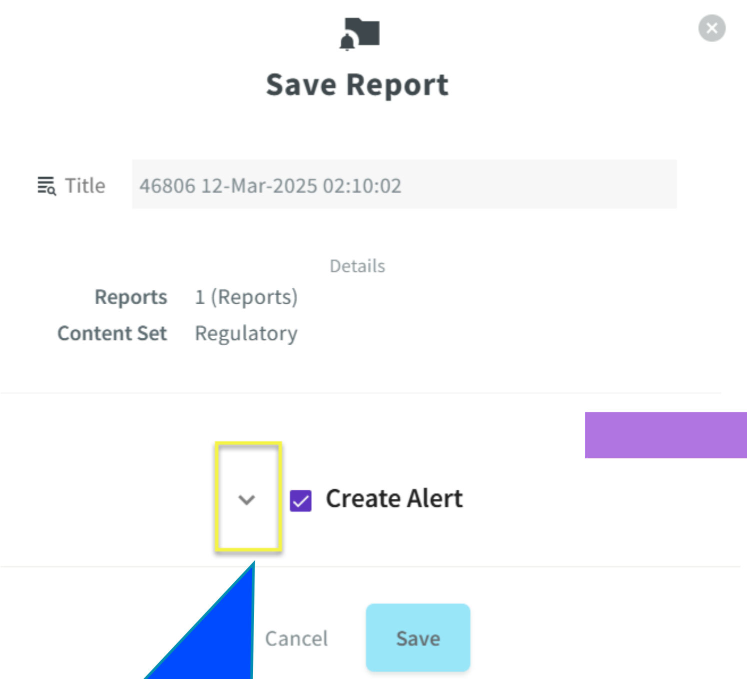
Abstract

This document covers aspects of GCP in China, with information of general principles, data handling and inspection.

Last Updated Date
02-Dec-2024

Added Date
09-Nov-2004

Document



Save Report

Title 46806 12-Mar-2025 02:10:02

Details

Reports 1 (Reports)

Content Set Regulatory

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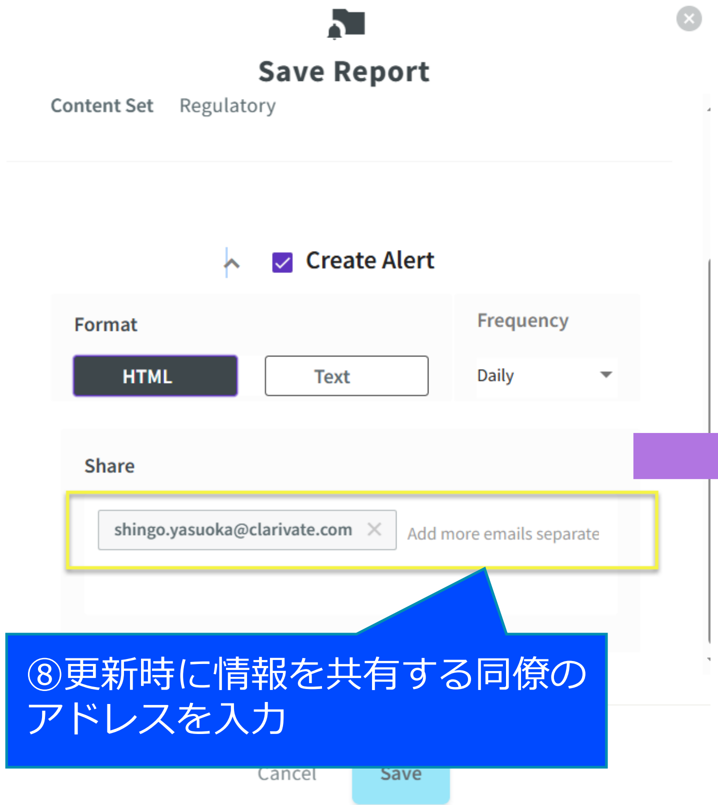
⑦チェックボタン横のアイコンをクリック



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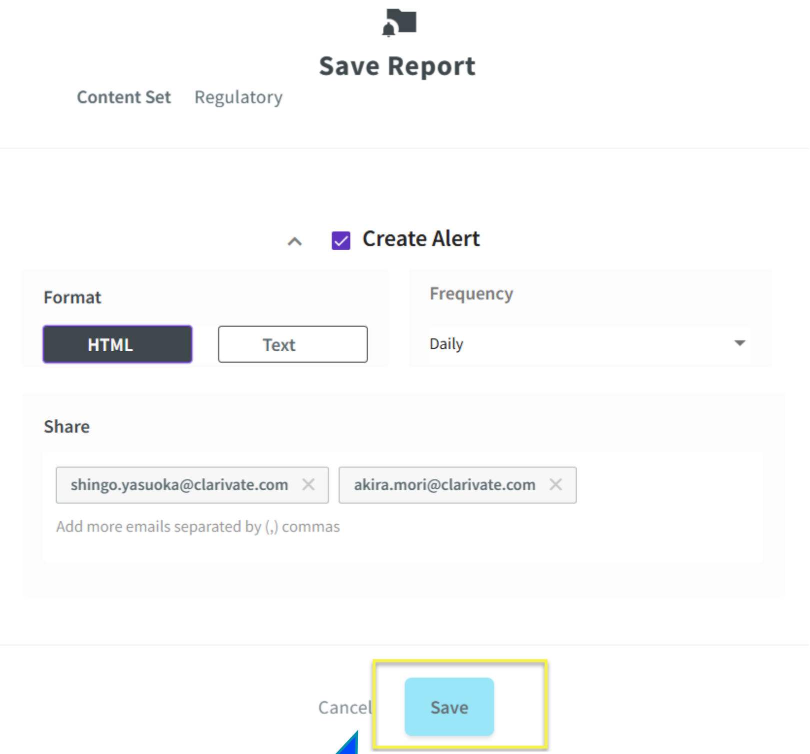
⑧更新時に情報を共有する同僚のアドレスを入力



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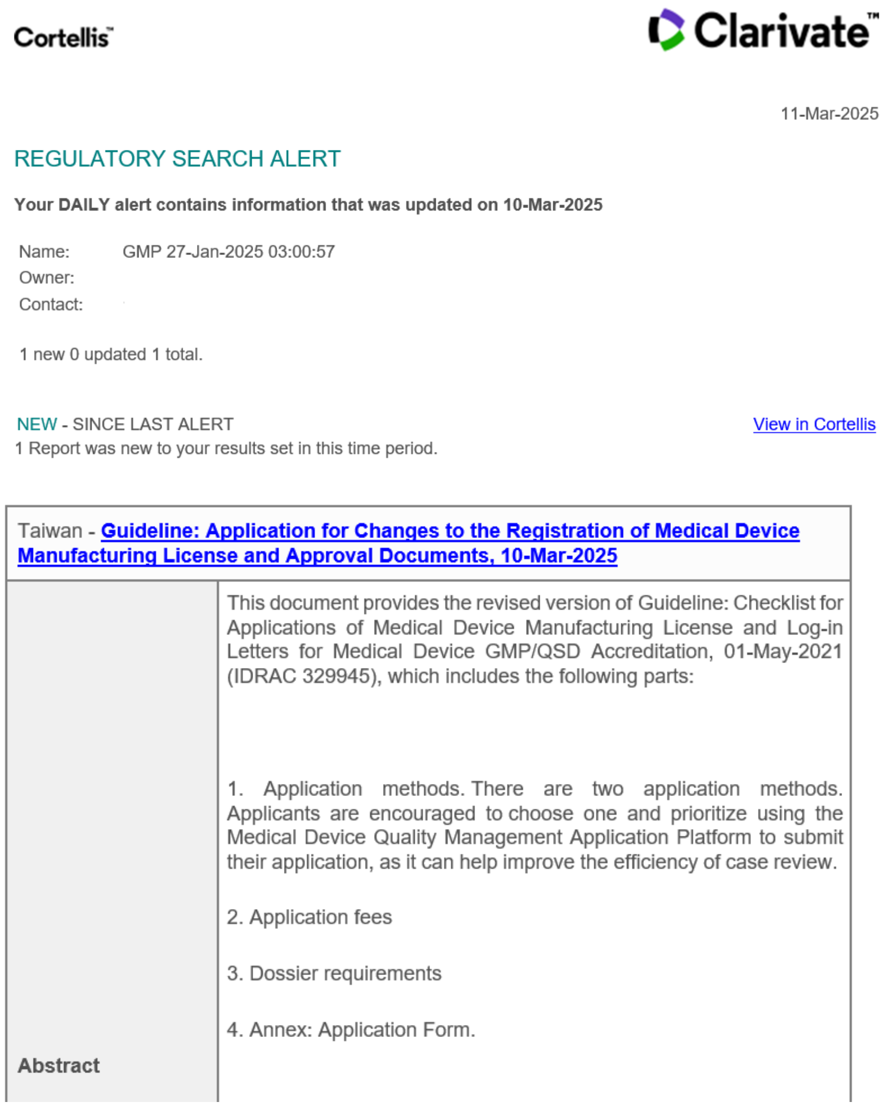
参考：アラートメールのイメージ



Cortellis™ Clarivate™

11-Mar-2025

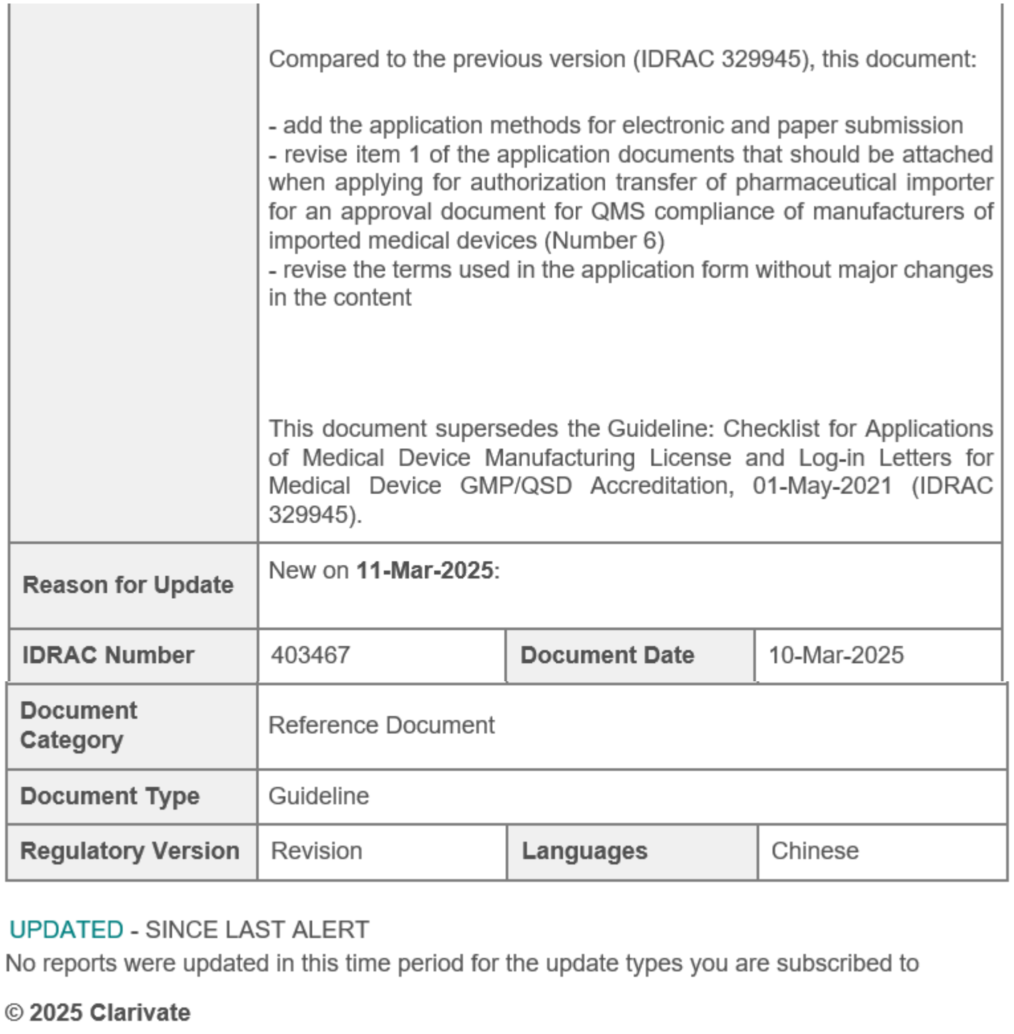
REGULATORY SEARCH ALERT

Your DAILY alert contains information that was updated on 10-Mar-2025

Name: GMP 27-Jan-2025 03:00:57
Owner:
Contact:

1 new 0 updated 1 total.

NEW - SINCE LAST ALERT View in Cortellis
1 Report was new to your results set in this time period.



Taiwan - **Guideline: Application for Changes to the Registration of Medical Device Manufacturing License and Approval Documents, 10-Mar-2025**			
Abstract	This document provides the revised version of Guideline: Checklist for Applications of Medical Device Manufacturing License and Log-in Letters for Medical Device GMP/QSD Accreditation, 01-May-2021 (IDRAC 329945), which includes the following parts: 1. Application methods. There are two application methods. Applicants are encouraged to choose one and prioritize using the Medical Device Quality Management Application Platform to submit their application, as it can help improve the efficiency of case review. 2. Application fees 3. Dossier requirements 4. Annex: Application Form. Compared to the previous version (IDRAC 329945), this document: - add the application methods for electronic and paper submission - revise item 1 of the application documents that should be attached when applying for authorization transfer of pharmaceutical importer for an approval document for QMS compliance of manufacturers of imported medical devices (Number 6) - revise the terms used in the application form without major changes in the content This document supersedes the Guideline: Checklist for Applications of Medical Device Manufacturing License and Log-in Letters for Medical Device GMP/QSD Accreditation, 01-May-2021 (IDRAC 329945).		
Reason for Update	New on **11-Mar-2025**:		
IDRAC Number	403467	**Document Date**	10-Mar-2025
Document Category	Reference Document		
Document Type	Guideline		
Regulatory Version	Revision	**Languages**	Chinese

UPDATED - SINCE LAST ALERT
No reports were updated in this time period for the update types you are subscribed to

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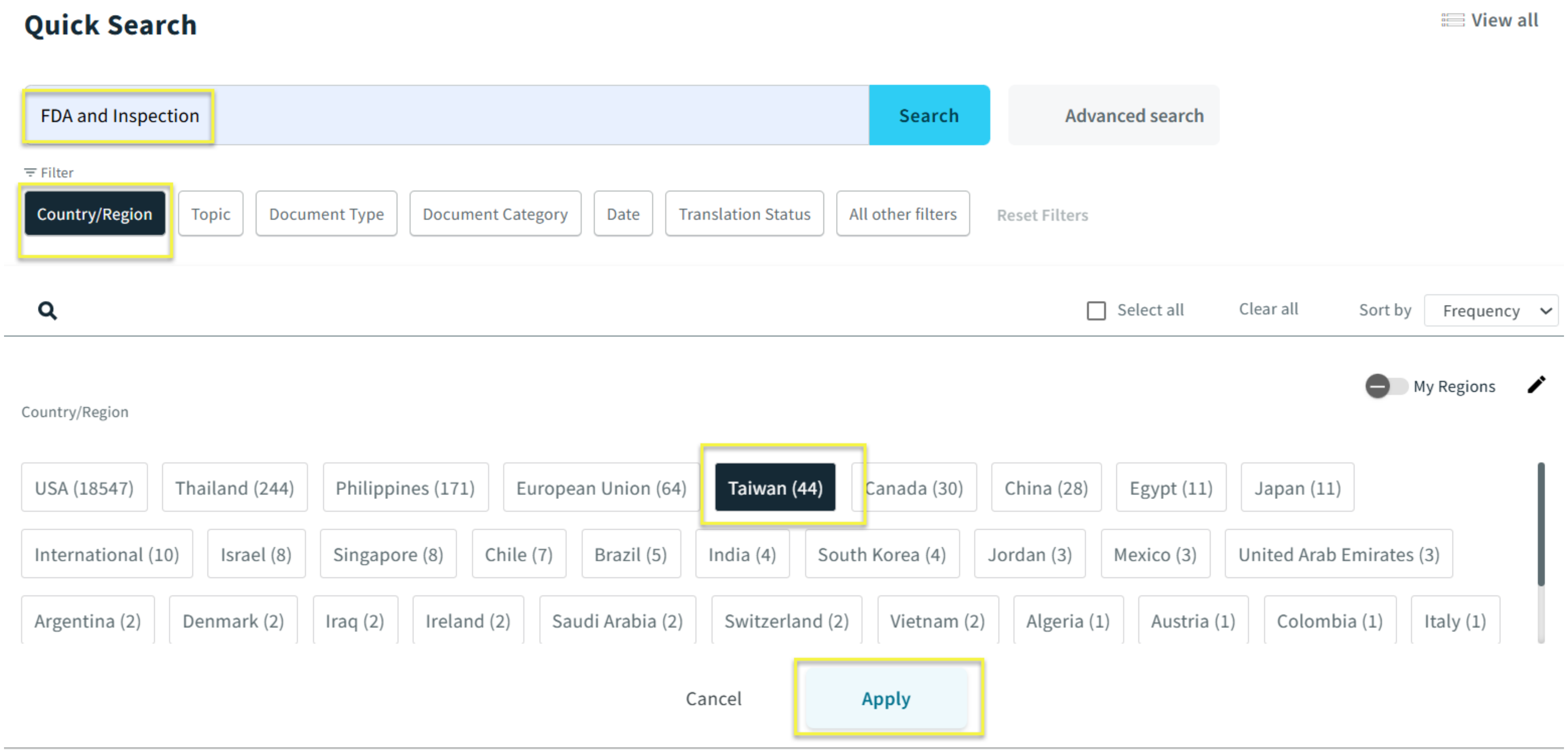
文書検索時の検索条件に対するアラート設定 (Alert on Query)

例：FDAおよびInspectionというキーワードをタイトルやアブストラクトに含む台湾の文書をモニターする。条件に合致した新規文書が収録された際には、通知がされる。



Quick Search

FDA and Inspection

Country/Region: Taiwan (44)

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Sort by
Frequency
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USA (18547)
Thailand (244)
Philippines (171)
European Union (64)
Taiwan (44)
Canada (30)
China (28)
Egypt (11)
Japan (11)
International (10)
Israel (8)
Singapore (8)
Chile (7)
Brazil (5)
India (4)
South Korea (4)
Jordan (3)
Mexico (3)
United Arab Emirates (3)
Argentina (2)
Denmark (2)
Iraq (2)
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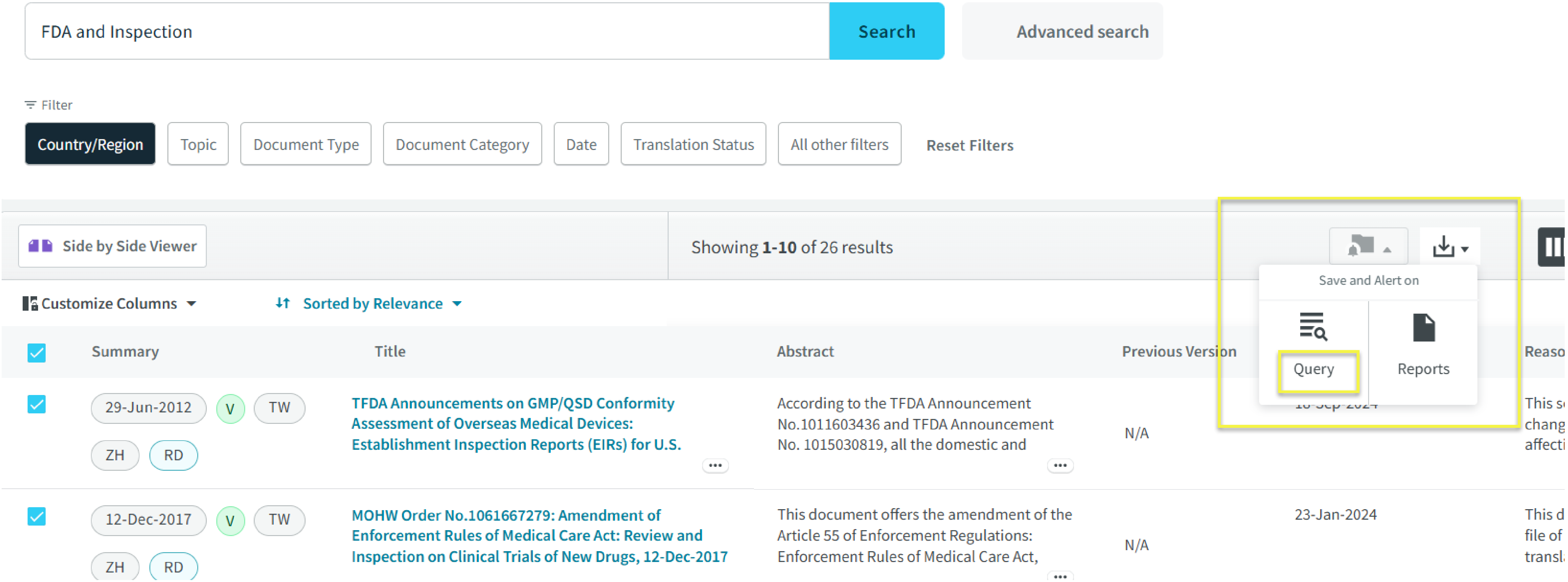
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Reports
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Sorted by Relevance

Showing **1-10** of 26 results

☑	Summary	Title	Abstract	Previous Version		Reaso
☑	29-Jun-2012 V TW ZH RD	TFDA Announcements on GMP/QSD Conformity Assessment of Overseas Medical Devices: Establishment Inspection Reports (EIRs) for U.S. •••	According to the TFDA Announcement No.1011603436 and TFDA Announcement No. 1015030819, all the domestic and •••	N/A		This s chang affecti
☑	12-Dec-2017 V TW ZH RD	MOHW Order No.1061667279: Amendment of Enforcement Rules of Medical Care Act: Review and Inspection on Clinical Trials of New Drugs, 12-Dec-2017	This document offers the amendment of the Article 55 of Enforcement Regulations: Enforcement Rules of Medical Care Act, •••	N/A	23-Jan-2024	This d file of transl

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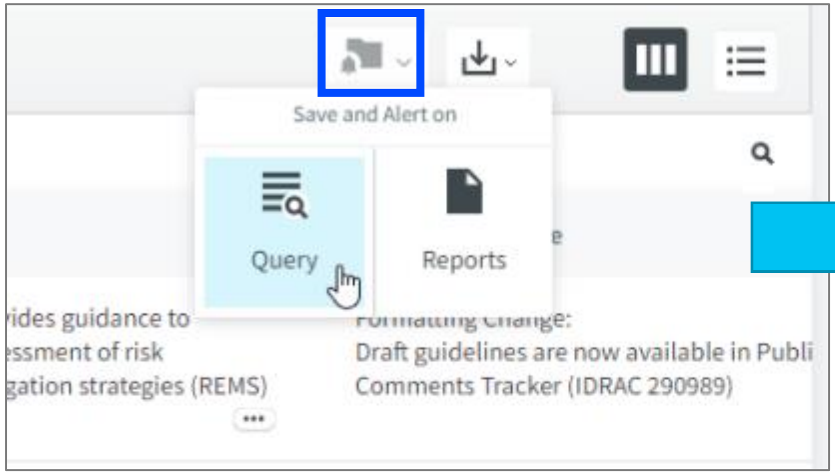
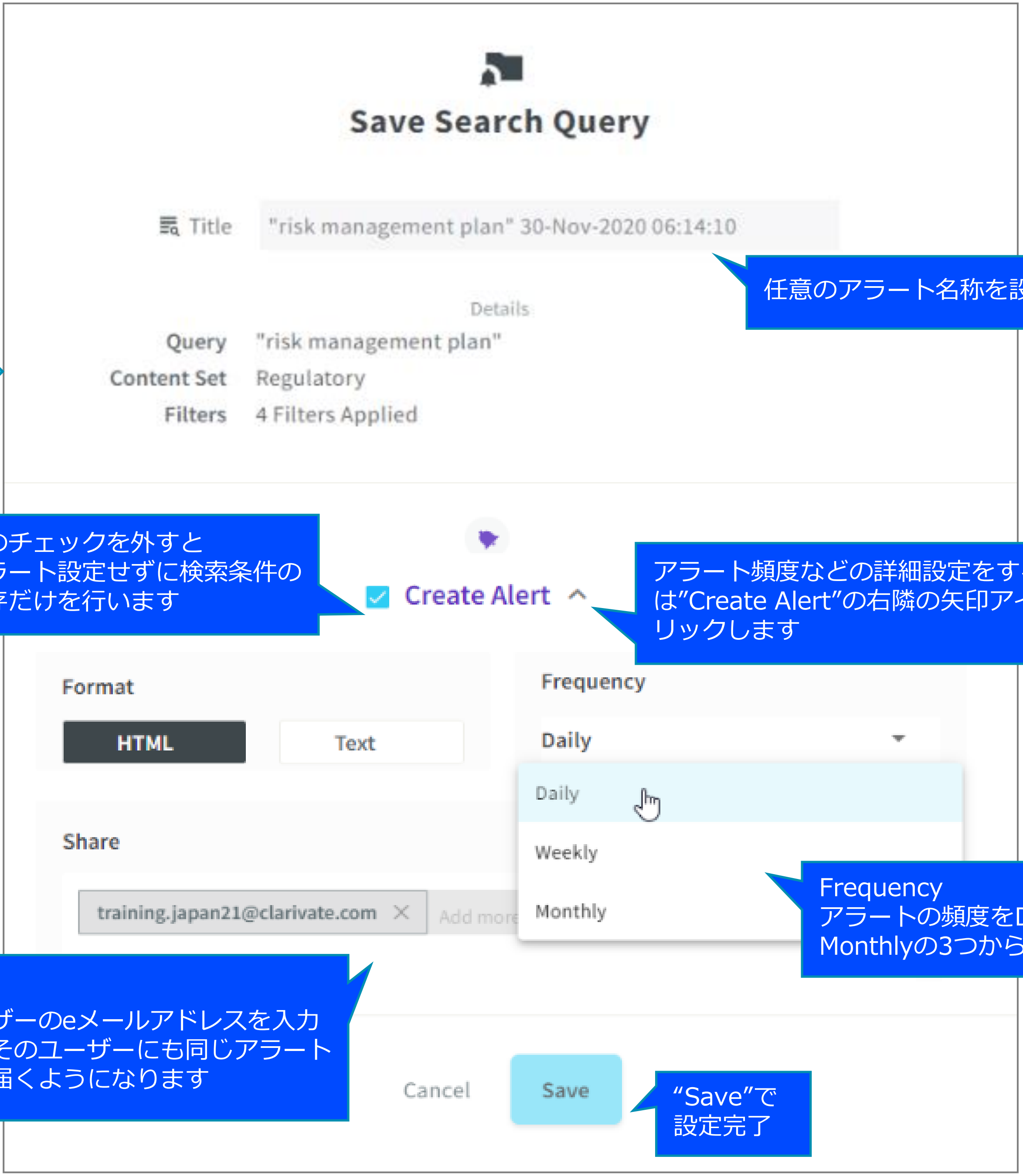
検索条件のアラート設定詳細 (Alert on Query)


Save and Alert on
Query
Reports
ides guidance to
ssment of risk
gation strategies (REMS)
Formatting Change:
Draft guidelines are now available in Publi
Comments Tracker (IDRAC 290989)

検索結果右上のSave and Alert on Queryをクリック

検索条件に合致する新規文書の収録を追跡するには検索結果画面でアラートを設定します



Save Search Query

Title: "risk management plan" 30-Nov-2020 06:14:10

Details

Query	"risk management plan"
Content Set	Regulatory
Filters	4 Filters Applied

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Frequency: Daily

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アラートの頻度をDaily, Weekly, Monthlyの3つから選択できます

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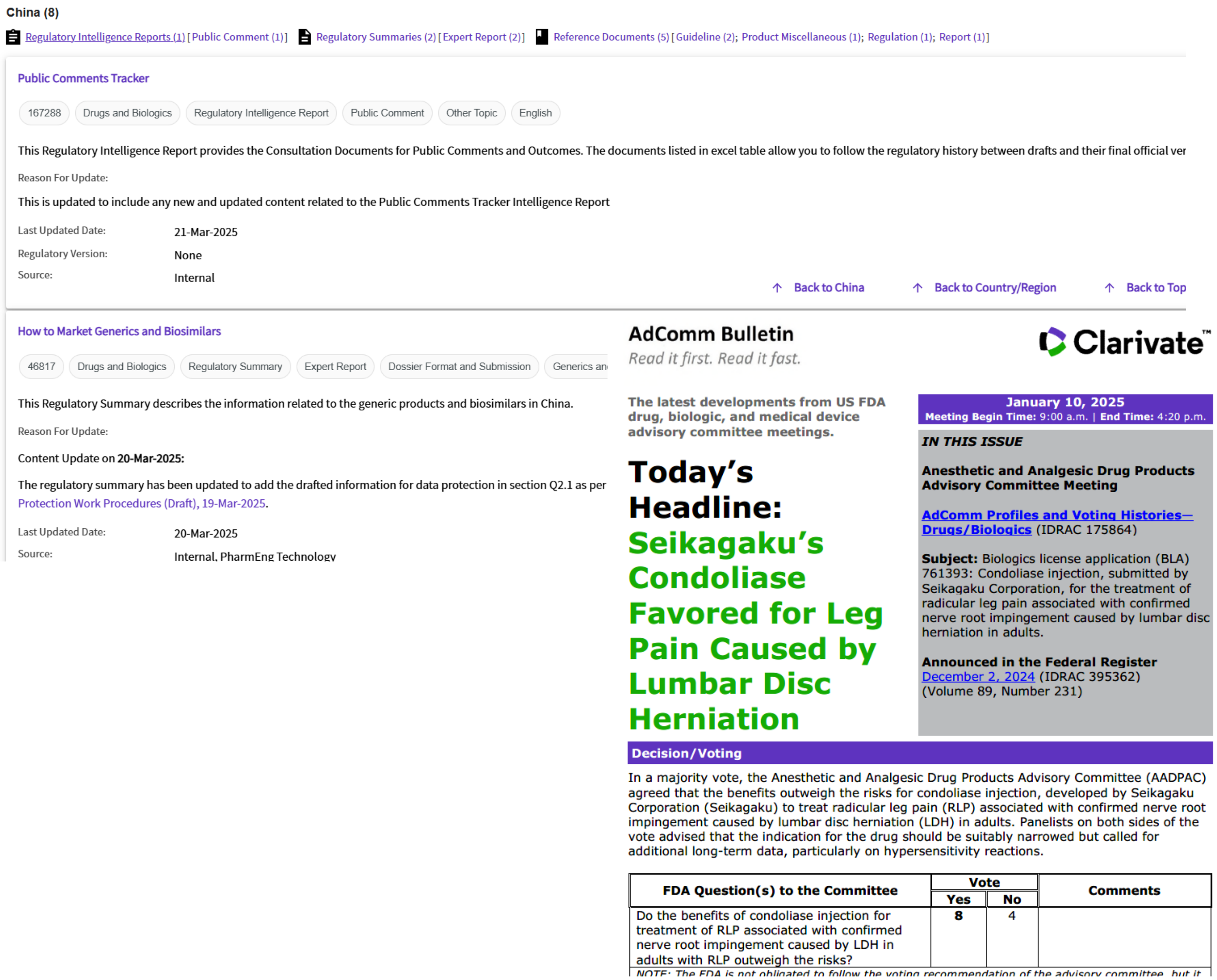
最新規制情報のモニター

速報eメールサービス

- Weekly Updates
  - 1週間ごとの最新規制、規制の変更を網羅
- Adcomm Bulletin
  - FDA諮問委員会の結論と製品申請の審査結果の分析を最速で入手



China (8)

Regulatory Intelligence Reports (1) [Public Comment (1)] Regulatory Summaries (2) [Expert Report (2)] Reference Documents (5) [Guideline (2); Product Miscellaneous (1); Regulation (1); Report (1)]

Public Comments Tracker

This Regulatory Intelligence Report provides the Consultation Documents for Public Comments and Outcomes. The documents listed in excel table allow you to follow the regulatory history between drafts and their final official ver

Reason For Update:

This is updated to include any new and updated content related to the Public Comments Tracker Intelligence Report

Last Updated Date: 21-Mar-2025
Regulatory Version: None
Source: Internal

How to Market Generics and Biosimilars

This Regulatory Summary describes the information related to the generic products and biosimilars in China.

Reason For Update:

Content Update on **20-Mar-2025:**

The regulatory summary has been updated to add the drafted information for data protection in section Q2.1 as per Protection Work Procedures (Draft), 19-Mar-2025.

Last Updated Date: 20-Mar-2025
Source: Internal, PharmEng Technology

AdComm Bulletin

Read it first. Read it fast.

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The latest developments from US FDA drug, biologic, and medical device advisory committee meetings.

January 10, 2025
Meeting Begin Time: 9:00 a.m. | **End Time:** 4:20 p.m.

IN THIS ISSUE

Anesthetic and Analgesic Drug Products Advisory Committee Meeting

AdComm Profiles and Voting Histories—Drugs/Biologics (IDRAC 175864)

Subject: Biologics license application (BLA) 761393: Condoliase injection, submitted by Seikagaku Corporation, for the treatment of radicular leg pain associated with confirmed nerve root impingement caused by lumbar disc herniation in adults.

Announced in the Federal Register
December 2, 2024 (IDRAC 395362)
(Volume 89, Number 231)

Today's Headline:
Seikagaku's Condoliase Favored for Leg Pain Caused by Lumbar Disc Herniation

Decision/Voting

In a majority vote, the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) agreed that the benefits outweigh the risks for condoliase injection, developed by Seikagaku Corporation (Seikagaku) to treat radicular leg pain (RLP) associated with confirmed nerve root impingement caused by lumbar disc herniation (LDH) in adults. Panelists on both sides of the vote advised that the indication for the drug should be suitably narrowed but called for additional long-term data, particularly on hypersensitivity reactions.

FDA Question(s) to the Committee	Vote		Comments
	Yes	No	
Do the benefits of condoliase injection for treatment of RLP associated with confirmed nerve root impingement caused by LDH in adults with RLP outweigh the risks?	**8**	4	

NOTE: The FDA is not obligated to follow the voting recommendation of the advisory committee, but it

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薬事規制業務に必要な実用的なインサイト

Cortellis Regulatory Intelligenceの付加価値コンテンツ

Source Documents

- 世界各国の規制当局・機関の公式文書
- 最新および過去バージョンを蓄積（バージョン管理情報付与）
- 全ての規制文書に英語のタイトル・抄録・更新理由等付加
- 現地語文書に機械翻訳を付与
- さらに一部の国は専門家による全文英訳を追加
- Medical Devices & IVDs: 16カ国
  China, South Korea, Taiwan, Japan, Brazil, Mexico, Israel, Russia, Argentina, Austria, France, Germany, Italy, Spain, Switzerland, Turkey

Regulatory Summaries

- 薬事専門家による各国の規制の枠組み・プロセスの英語解説文
- 標準化されたフォーマット
- 主要な規制文書をリスト
- 規制変更により随時更新

Regulatory Intelligence Reports

- 様々な重要トピックについて実務に役立つ規制分析レポート
  - 規制変更追跡
  - 競合品承認情報
  - FDA査察情報　等

Global Regulatory Comparisons

- 重要トピックに関する世界各国の規制比較表
- 規制の共通点・相違点を簡単に把握
- 主要な規制文書へのリンクで簡単に詳細を確認可能
- 随時更新

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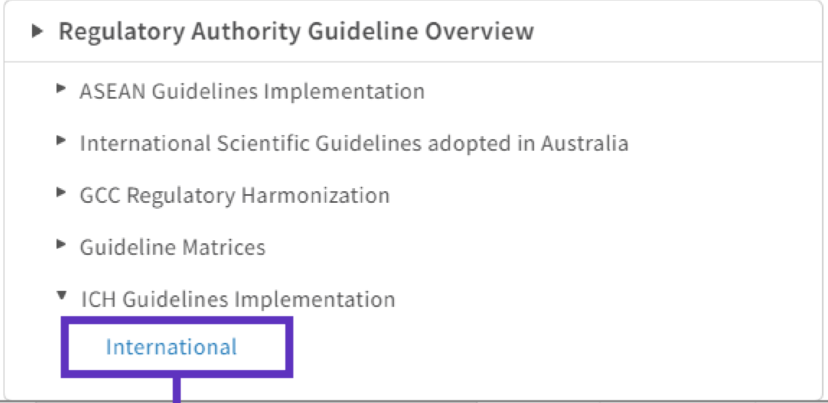
コンテンツ例

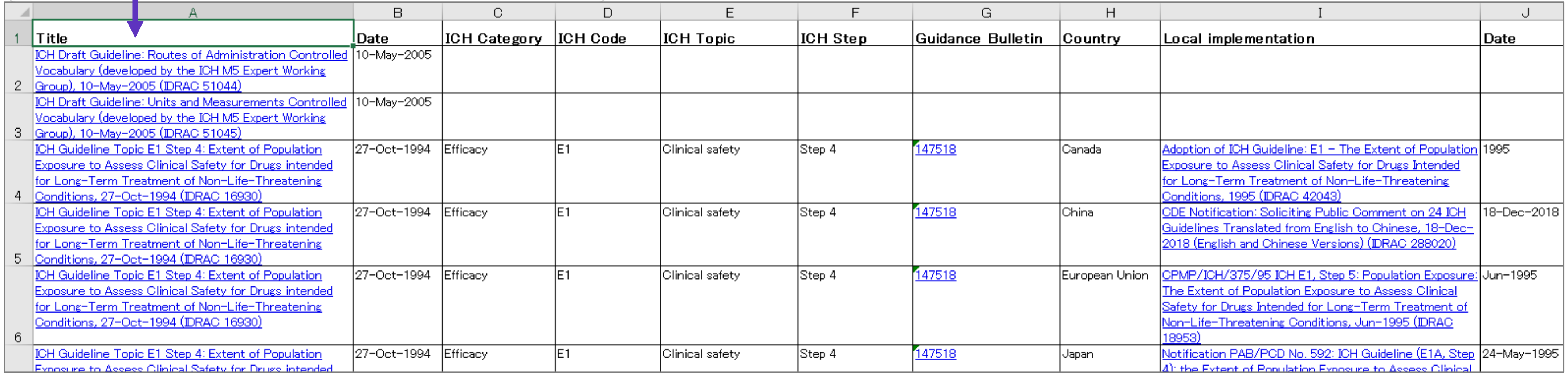
• ICH Guidelines Implementationを活用したICHガイドラインの最新情報、ローカルへの取り入れ状況のトラッキング

- **Intelligence Reports**は規制の最新情報、他社の査察事例など、**様々な分析レポートを活用した情報収集**が可能
- ICH Guidelines Implementationでは現状ドラフト段階のものを含むICHガイドラインの一覧、現在のSTEP、日米欧に加え、カナダ、中国、韓国の取入れ状況をモニタリングできます。



▶ Regulatory Authority Guideline Overview

- ▸ ASEAN Guidelines Implementation
- ▸ International Scientific Guidelines adopted in Australia
- ▸ GCC Regulatory Harmonization
- ▸ Guideline Matrices
- ▾ ICH Guidelines Implementation
  - International



	A	B	C	D	E	F	G	H	I	J
1	**Title**	**Date**	**ICH Category**	**ICH Code**	**ICH Topic**	**ICH Step**	**Guidance Bulletin**	**Country**	**Local implementation**	**Date**
2	ICH Draft Guideline: Routes of Administration Controlled Vocabulary (developed by the ICH M5 Expert Working Group), 10-May-2005 (IDRAC 51044)	10-May-2005								
3	ICH Draft Guideline: Units and Measurements Controlled Vocabulary (developed by the ICH M5 Expert Working Group), 10-May-2005 (IDRAC 51045)	10-May-2005								
4	ICH Guideline Topic E1 Step 4: Extent of Population Exposure to Assess Clinical Safety for Drugs intended for Long-Term Treatment of Non-Life-Threatening Conditions, 27-Oct-1994 (IDRAC 16930)	27-Oct-1994	Efficacy	E1	Clinical safety	Step 4	147518	Canada	Adoption of ICH Guideline: E1 – The Extent of Population Exposure to Assess Clinical Safety for Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions, 1995 (IDRAC 42043)	1995
5	ICH Guideline Topic E1 Step 4: Extent of Population Exposure to Assess Clinical Safety for Drugs intended for Long-Term Treatment of Non-Life-Threatening Conditions, 27-Oct-1994 (IDRAC 16930)	27-Oct-1994	Efficacy	E1	Clinical safety	Step 4	147518	China	CDE Notification: Soliciting Public Comment on 24 ICH Guidelines Translated from English to Chinese, 18-Dec-2018 (English and Chinese Versions) (IDRAC 288020)	18-Dec-2018
6	ICH Guideline Topic E1 Step 4: Extent of Population Exposure to Assess Clinical Safety for Drugs intended for Long-Term Treatment of Non-Life-Threatening Conditions, 27-Oct-1994 (IDRAC 16930)	27-Oct-1994	Efficacy	E1	Clinical safety	Step 4	147518	European Union	CPMP/ICH/375/95 ICH E1, Step 5: Population Exposure: The Extent of Population Exposure to Assess Clinical Safety for Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions, Jun-1995 (IDRAC 18953)	Jun-1995
	ICH Guideline Topic E1 Step 4: Extent of Population Exposure to Assess Clinical Safety for Drugs intended	27-Oct-1994	Efficacy	E1	Clinical safety	Step 4	147518	Japan	Notification PAB/PCD No. 592: ICH Guideline (E1A, Step 4): the Extent of Population Exposure to Assess Clinical	24-May-1995

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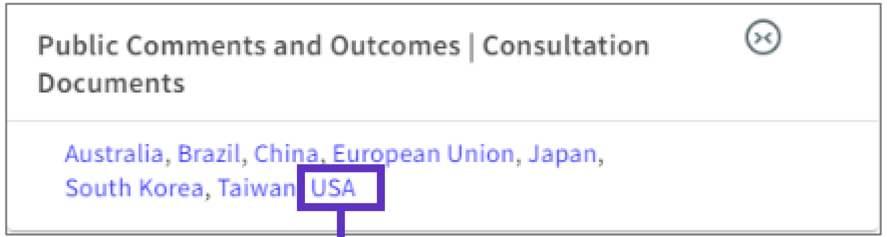
コンテンツ例

- Public Comments Trackerを使用し、意見募集中の最新ドラフトガイドラインやその最終バージョンを一括で確認する

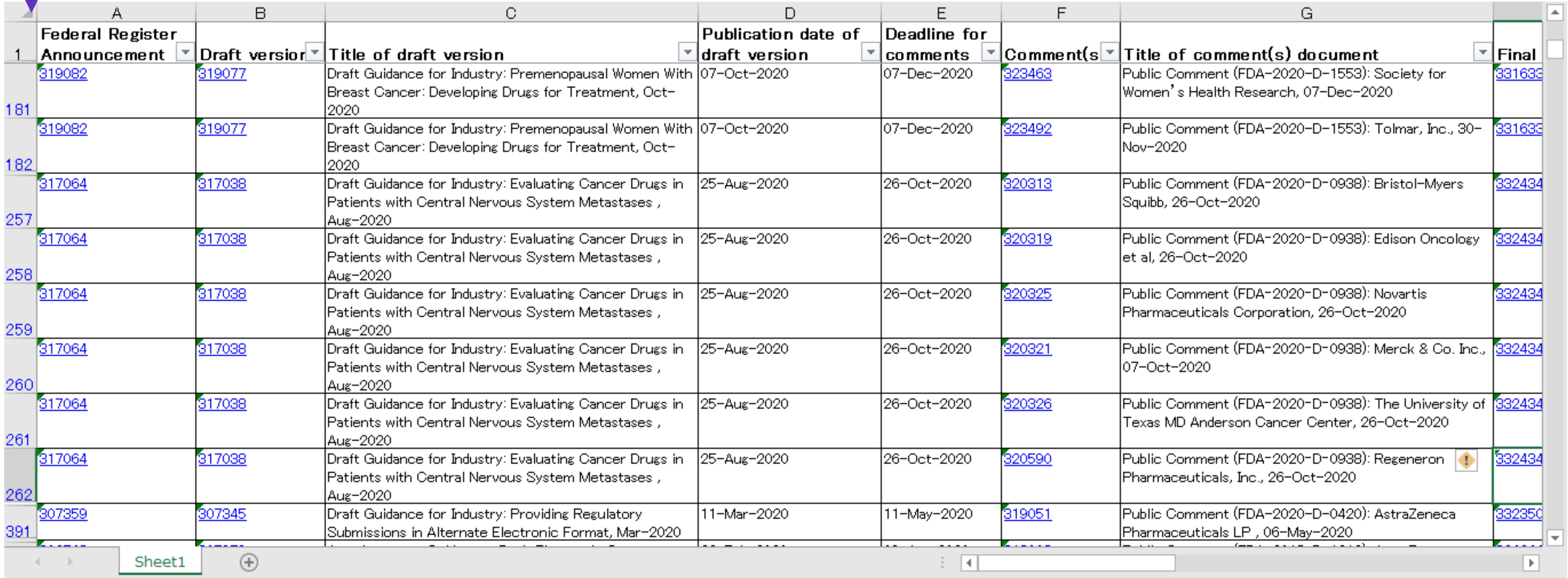
- パブリックコメントの対象となったガイドラインのドラフトおよび最終版の最新状況を確認
- 最新のドラフトガイドラインを入手して今後の規制変更に備える



Public Comments and Outcomes | Consultation Documents

Australia, Brazil, China, European Union, Japan, South Korea, Taiwan, USA

Regulatory Intelligence Reportのトピック一覧から Public Comments and Outcomes > 国名をクリック



	A	B	C	D	E	F	G	
1	Federal Register Announcement	Draft version	Title of draft version	Publication date of draft version	Deadline for comments	Comment(s	Title of comment(s) document	Final
181	319082	319077	Draft Guidance for Industry: Premenopausal Women With Breast Cancer: Developing Drugs for Treatment, Oct-2020	07-Oct-2020	07-Dec-2020	323463	Public Comment (FDA-2020-D-1553): Society for Women's Health Research, 07-Dec-2020	331633
182	319082	319077	Draft Guidance for Industry: Premenopausal Women With Breast Cancer: Developing Drugs for Treatment, Oct-2020	07-Oct-2020	07-Dec-2020	323492	Public Comment (FDA-2020-D-1553): Tolmar, Inc., 30-Nov-2020	331633
257	317064	317038	Draft Guidance for Industry: Evaluating Cancer Drugs in Patients with Central Nervous System Metastases , Aug-2020	25-Aug-2020	26-Oct-2020	320313	Public Comment (FDA-2020-D-0938): Bristol-Myers Squibb, 26-Oct-2020	332434
258	317064	317038	Draft Guidance for Industry: Evaluating Cancer Drugs in Patients with Central Nervous System Metastases , Aug-2020	25-Aug-2020	26-Oct-2020	320319	Public Comment (FDA-2020-D-0938): Edison Oncology et al, 26-Oct-2020	332434
259	317064	317038	Draft Guidance for Industry: Evaluating Cancer Drugs in Patients with Central Nervous System Metastases , Aug-2020	25-Aug-2020	26-Oct-2020	320325	Public Comment (FDA-2020-D-0938): Novartis Pharmaceuticals Corporation, 26-Oct-2020	332434
260	317064	317038	Draft Guidance for Industry: Evaluating Cancer Drugs in Patients with Central Nervous System Metastases , Aug-2020	25-Aug-2020	26-Oct-2020	320321	Public Comment (FDA-2020-D-0938): Merck & Co. Inc., 07-Oct-2020	332434
261	317064	317038	Draft Guidance for Industry: Evaluating Cancer Drugs in Patients with Central Nervous System Metastases , Aug-2020	25-Aug-2020	26-Oct-2020	320326	Public Comment (FDA-2020-D-0938): The University of Texas MD Anderson Cancer Center, 26-Oct-2020	332434
262	317064	317038	Draft Guidance for Industry: Evaluating Cancer Drugs in Patients with Central Nervous System Metastases , Aug-2020	25-Aug-2020	26-Oct-2020	320590	Public Comment (FDA-2020-D-0938): Regeneron Pharmaceuticals, Inc., 26-Oct-2020	332434
391	307359	307345	Draft Guidance for Industry: Providing Regulatory Submissions in Alternate Electronic Format, Mar-2020	11-Mar-2020	11-May-2020	319051	Public Comment (FDA-2020-D-0420): AstraZeneca Pharmaceuticals LP , 06-May-2020	332350

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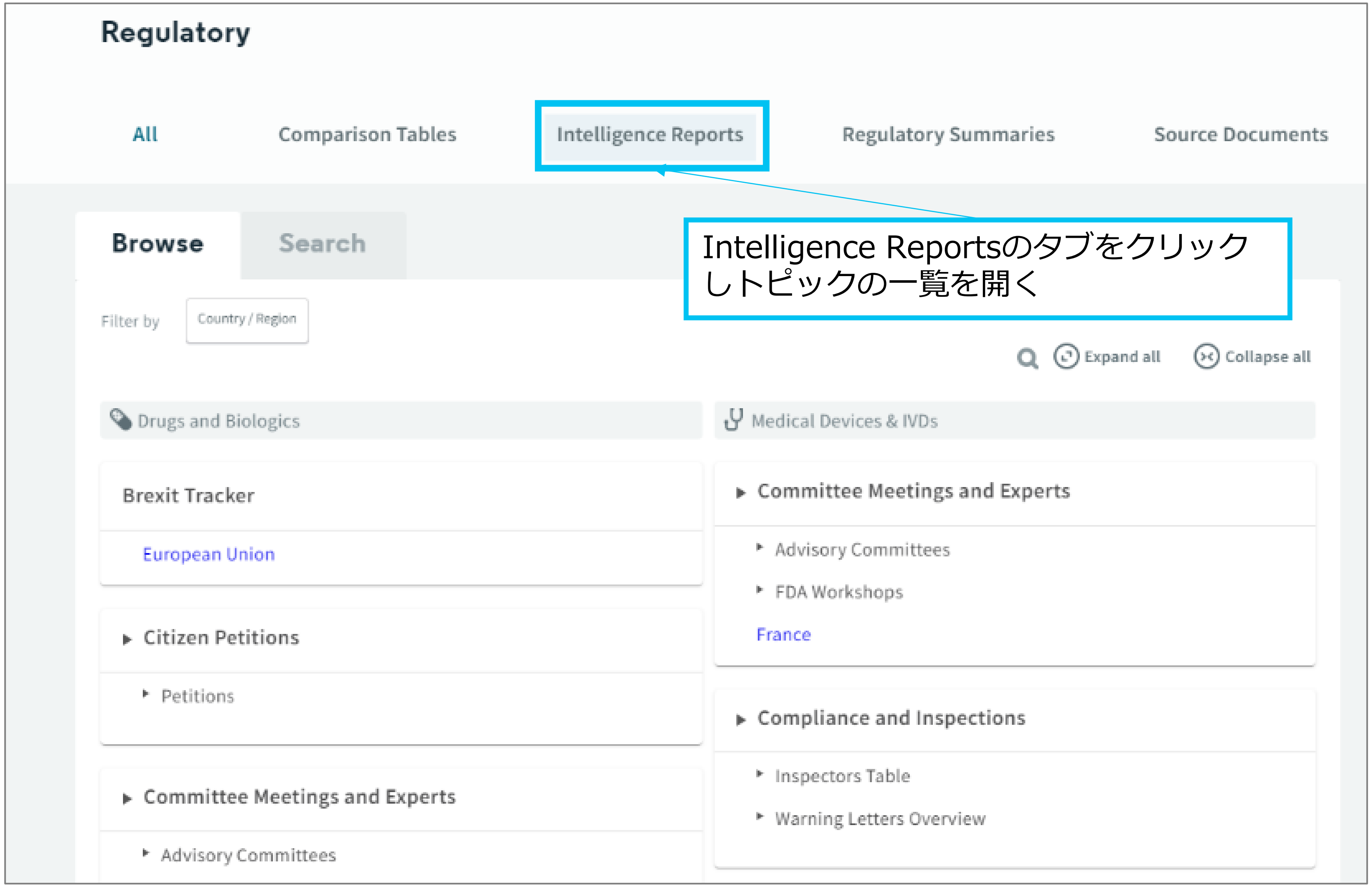

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European Union

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Medical Devices & IVDs

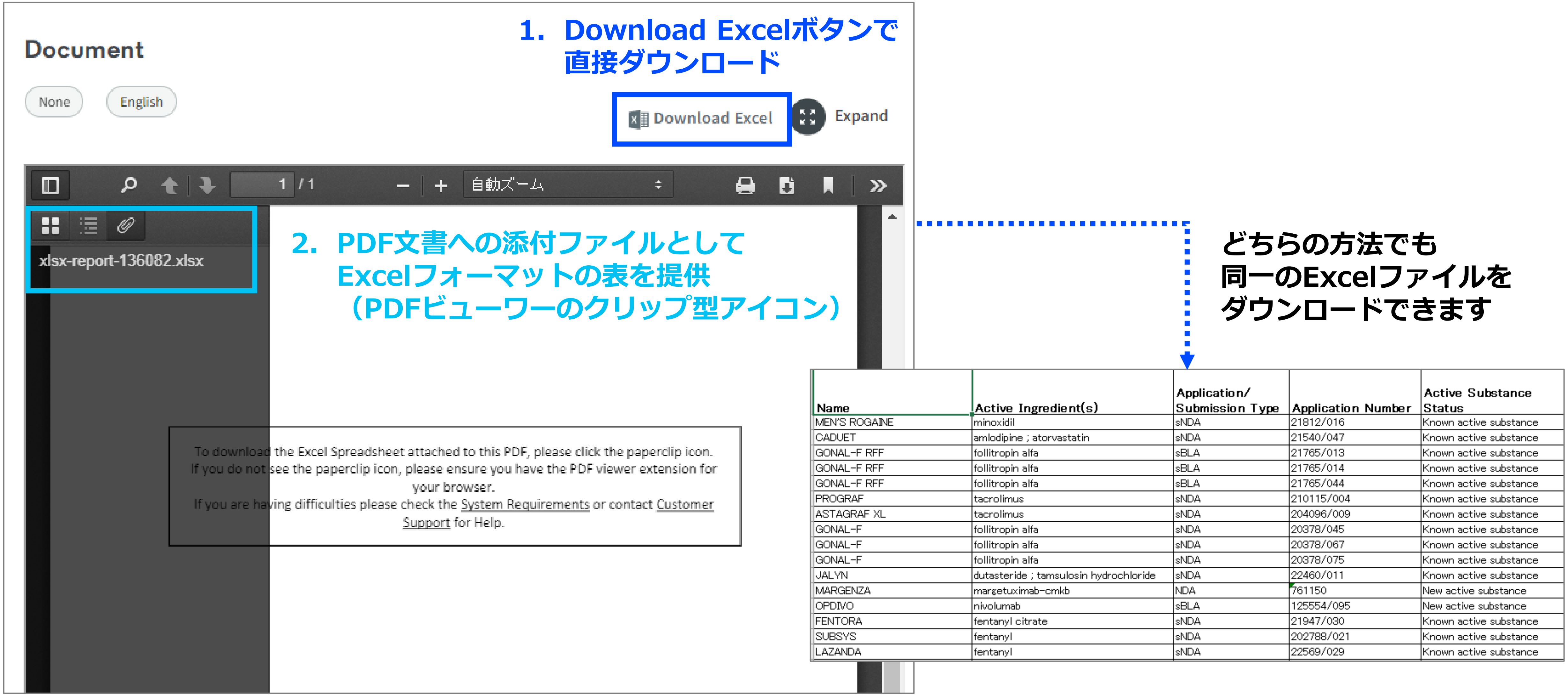
- Committee Meetings and Experts
  - Advisory Committees
  - FDA Workshops

France

- Compliance and Inspections
  - Inspectors Table
  - Warning Letters Overview

Intelligence Reportsのタブをクリックしトピックの一覧を開く

参考：Intelligence Reports – 2つのExcelファイルダウンロード方法



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2. PDF文書への添付ファイルとしてExcelフォーマットの表を提供（PDFビューワーのクリップ型アイコン）

To download the Excel Spreadsheet attached to this PDF, please click the paperclip icon. If you do not see the paperclip icon, please ensure you have the PDF viewer extension for your browser.
If you are having difficulties please check the System Requirements or contact Customer Support for Help.

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ダウンロードできます

Name	Active Ingredient(s)	Application/ Submission Type	Application Number	Active Substance Status
MEN'S ROGAINE	minoxidil	sNDA	21812/016	Known active substance
CADUET	amlodipine ; atorvastatin	sNDA	21540/047	Known active substance
GONAL-F RFF	follitropin alfa	sBLA	21765/013	Known active substance
GONAL-F RFF	follitropin alfa	sBLA	21765/014	Known active substance
GONAL-F RFF	follitropin alfa	sBLA	21765/044	Known active substance
PROGRAF	tacrolimus	sNDA	210115/004	Known active substance
ASTAGRAF XL	tacrolimus	sNDA	204096/009	Known active substance
GONAL-F	follitropin alfa	sNDA	20378/045	Known active substance
GONAL-F	follitropin alfa	sNDA	20378/067	Known active substance
GONAL-F	follitropin alfa	sNDA	20378/075	Known active substance
JALYN	dutasteride ; tamsulosin hydrochloride	sNDA	22460/011	Known active substance
MARGENZA	margetuximab-cmkb	NDA	761150	New active substance
OPDIVO	nivolumab	sBLA	125554/095	New active substance
FENTORA	fentanyl citrate	sNDA	21947/030	Known active substance
SUBSYS	fentanyl	sNDA	202788/021	Known active substance
LAZANDA	fentanyl	sNDA	22569/029	Known active substance

4. 国別の規制要件を横断的に整理、比較するには？

- 各国規制の解説文、規制の比較表コンテンツの活用

薬事規制業務に必要な実用的なインサイト

Cortellis Regulatory Intelligenceの付加価値コンテンツ

Source Documents

- 世界各国の規制当局・機関の公式文書
- 最新および過去バージョンを蓄積（バージョン管理情報付与）
- 全ての規制文書に英語のタイトル・抄録・更新理由等付加
- 現地語文書に機械翻訳を付与
- さらに一部の国は専門家による全文英訳を追加
- Medical Devices & IVDs: 16カ国
  China, South Korea, Taiwan, Japan, Brazil, Mexico, Israel, Russia, Argentina, Austria, France, Germany, Italy, Spain, Switzerland, Turkey

Regulatory Summaries

- 薬事専門家による各国の規制の枠組み・プロセスの英語解説文
- 標準化されたフォーマット
- 主要な規制文書をリスト
- 規制変更により随時更新

Regulatory Intelligence Reports

- 様々な重要トピックについて実務に役立つ規制分析レポート

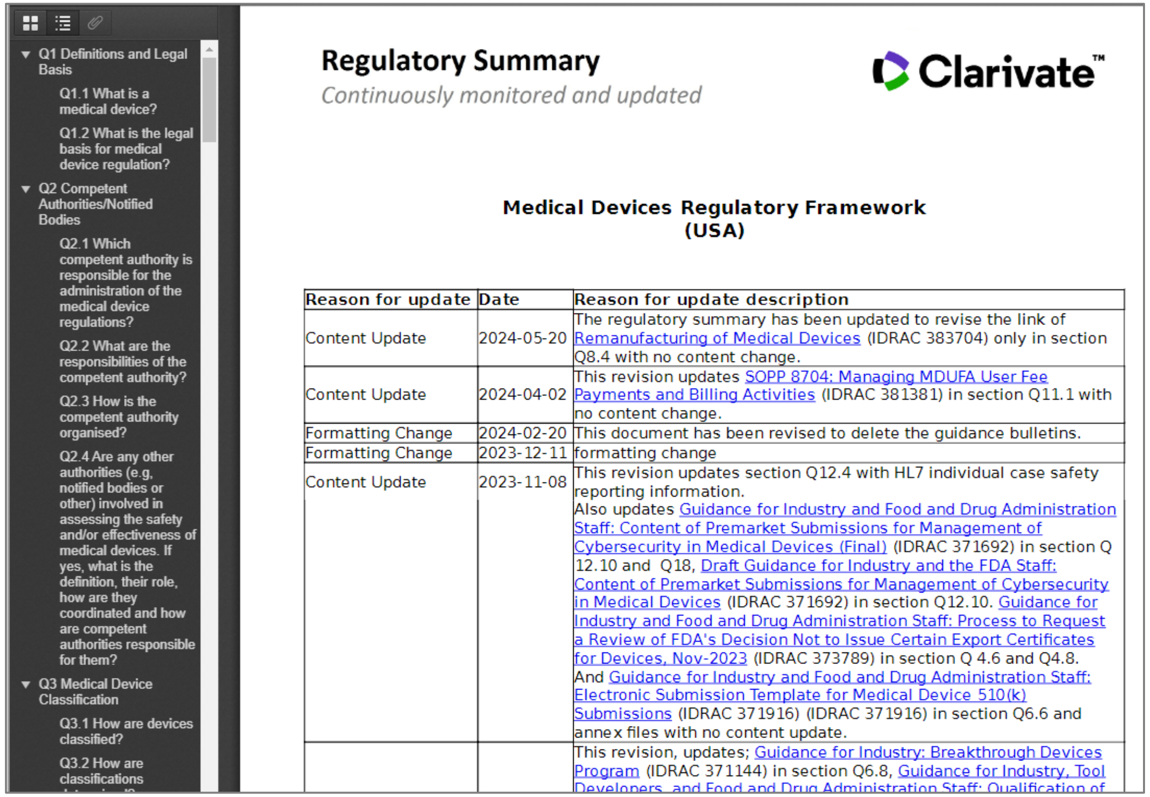
- 規制変更追跡
- 競合品承認情報
- FDA査察情報　等

Global Regulatory Comparisons

- 重要トピックに関する世界各国の規制比較表
- 規制の共通点・相違点を簡単に把握
- 主要な規制文書へのリンクで簡単に詳細を確認可能
- 随時更新

コンテンツ例　各国規制について統一書式で用意された英語での解説文を活用し、規制の全体像を把握

- **Regulatory Summary**は医療機器や体外診断薬の**開発段階～市販後までの様々な規制対応プロセスを英語で解説**
- 各国で同じトピックの解説文を統一された文書構成で用意



- Q1 Definitions and Legal Basis
  - Q1.1 What is a medical device?
  - Q1.2 What is the legal basis for medical device regulation?
- Q2 Competent Authorities/Notified Bodies
  - Q2.1 Which competent authority is responsible for the administration of the medical device regulations?
  - Q2.2 What are the responsibilities of the competent authority?
  - Q2.3 How is the competent authority organised?
  - Q2.4 Are any other authorities (e.g, notified bodies or other) involved in assessing the safety and/or effectiveness of medical devices. If yes, what is the definition, their role, how are they coordinated and how are competent authorities responsible for them?
- Q3 Medical Device Classification
  - Q3.1 How are devices classified?
  - Q3.2 How are classifications

Regulatory Summary

Continuously monitored and updated

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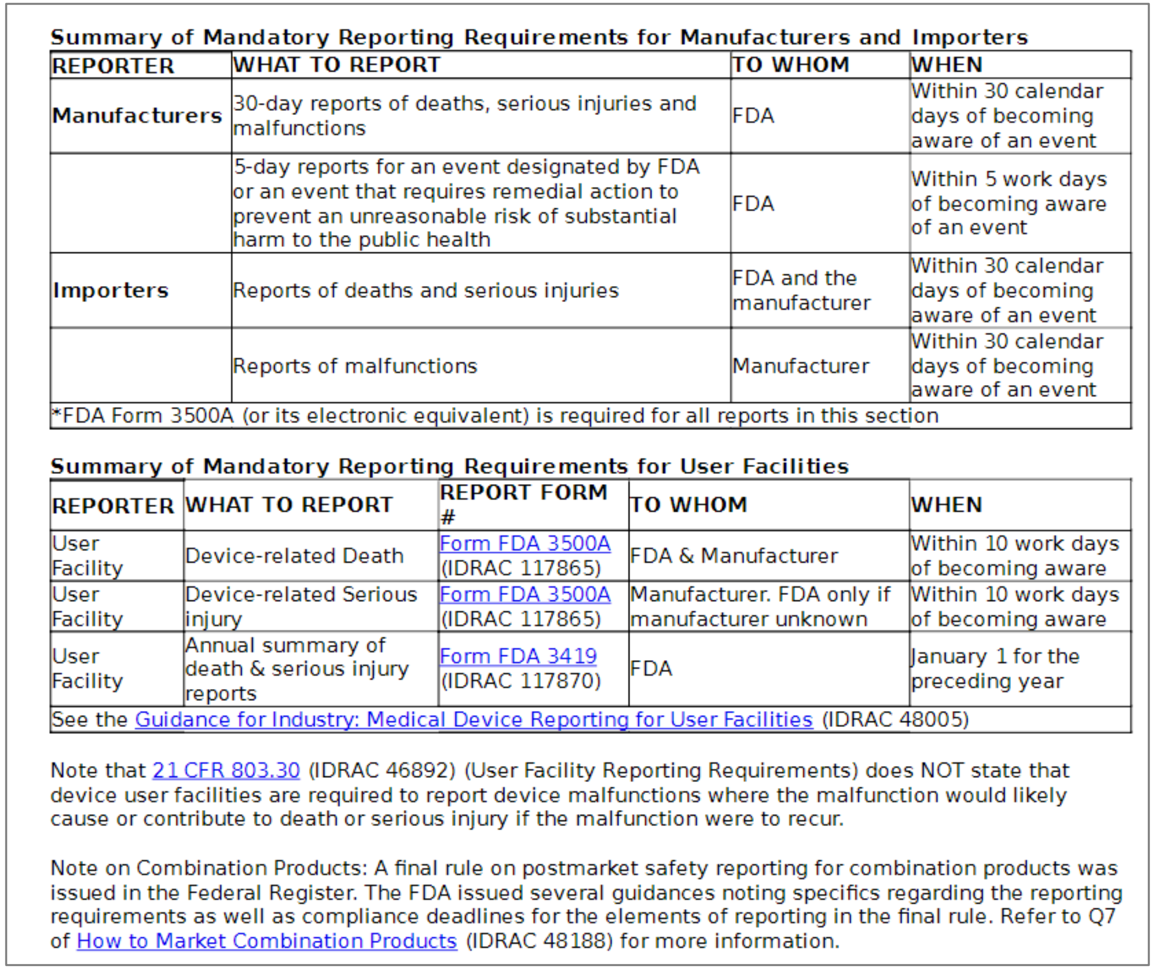
Medical Devices Regulatory Framework
(USA)

Reason for update	Date	Reason for update description
Content Update	2024-05-20	The regulatory summary has been updated to revise the link of Remanufacturing of Medical Devices (IDRAC 383704) only in section Q8.4 with no content change.
Content Update	2024-04-02	This revision updates SOPP 8704: Managing MDUFA User Fee Payments and Billing Activities (IDRAC 381381) in section Q11.1 with no content change.
Formatting Change	2024-02-20	This document has been revised to delete the guidance bulletins.
Formatting Change	2023-12-11	formatting change
Content Update	2023-11-08	This revision updates section Q12.4 with HL7 individual case safety reporting information. Also updates Guidance for Industry and Food and Drug Administration Staff: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (Final) (IDRAC 371692) in section Q 12.10 and Q18, Draft Guidance for Industry and the FDA Staff: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (IDRAC 371692) in section Q12.10. Guidance for Industry and Food and Drug Administration Staff: Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices, Nov-2023 (IDRAC 373789) in section Q 4.6 and Q4.8. And Guidance for Industry and Food and Drug Administration Staff: Electronic Submission Template for Medical Device 510(k) Submissions (IDRAC 371916) (IDRAC 371916) in section Q6.6 and annex files with no content update.
		This revision, updates; Guidance for Industry: Breakthrough Devices Program (IDRAC 371144) in section Q6.8, Guidance for Industry, Tool Developers, and Food and Drug Administration Staff: Qualification of

現地の規制変更に合わせて解説内容も随時アップデート



Summary of Mandatory Reporting Requirements for Manufacturers and Importers

REPORTER	WHAT TO REPORT	TO WHOM	WHEN
Manufacturers	30-day reports of deaths, serious injuries and malfunctions	FDA	Within 30 calendar days of becoming aware of an event
	5-day reports for an event designated by FDA or an event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health	FDA	Within 5 work days of becoming aware of an event
Importers	Reports of deaths and serious injuries	FDA and the manufacturer	Within 30 calendar days of becoming aware of an event
	Reports of malfunctions	Manufacturer	Within 30 calendar days of becoming aware of an event
*FDA Form 3500A (or its electronic equivalent) is required for all reports in this section			

Summary of Mandatory Reporting Requirements for User Facilities

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
User Facility	Device-related Death	Form FDA 3500A (IDRAC 117865)	FDA & Manufacturer	Within 10 work days of becoming aware
User Facility	Device-related Serious injury	Form FDA 3500A (IDRAC 117865)	Manufacturer. FDA only if manufacturer unknown	Within 10 work days of becoming aware
User Facility	Annual summary of death & serious injury reports	Form FDA 3419 (IDRAC 117870)	FDA	January 1 for the preceding year
See the Guidance for Industry: Medical Device Reporting for User Facilities (IDRAC 48005)				

Note that 21 CFR 803.30 (IDRAC 46892) (User Facility Reporting Requirements) does NOT state that device user facilities are required to report device malfunctions where the malfunction would likely cause or contribute to death or serious injury if the malfunction were to recur.

Note on Combination Products: A final rule on postmarket safety reporting for combination products was issued in the Federal Register. The FDA issued several guidances noting specifics regarding the reporting requirements as well as compliance deadlines for the elements of reporting in the final rule. Refer to Q7 of How to Market Combination Products (IDRAC 48188) for more information.

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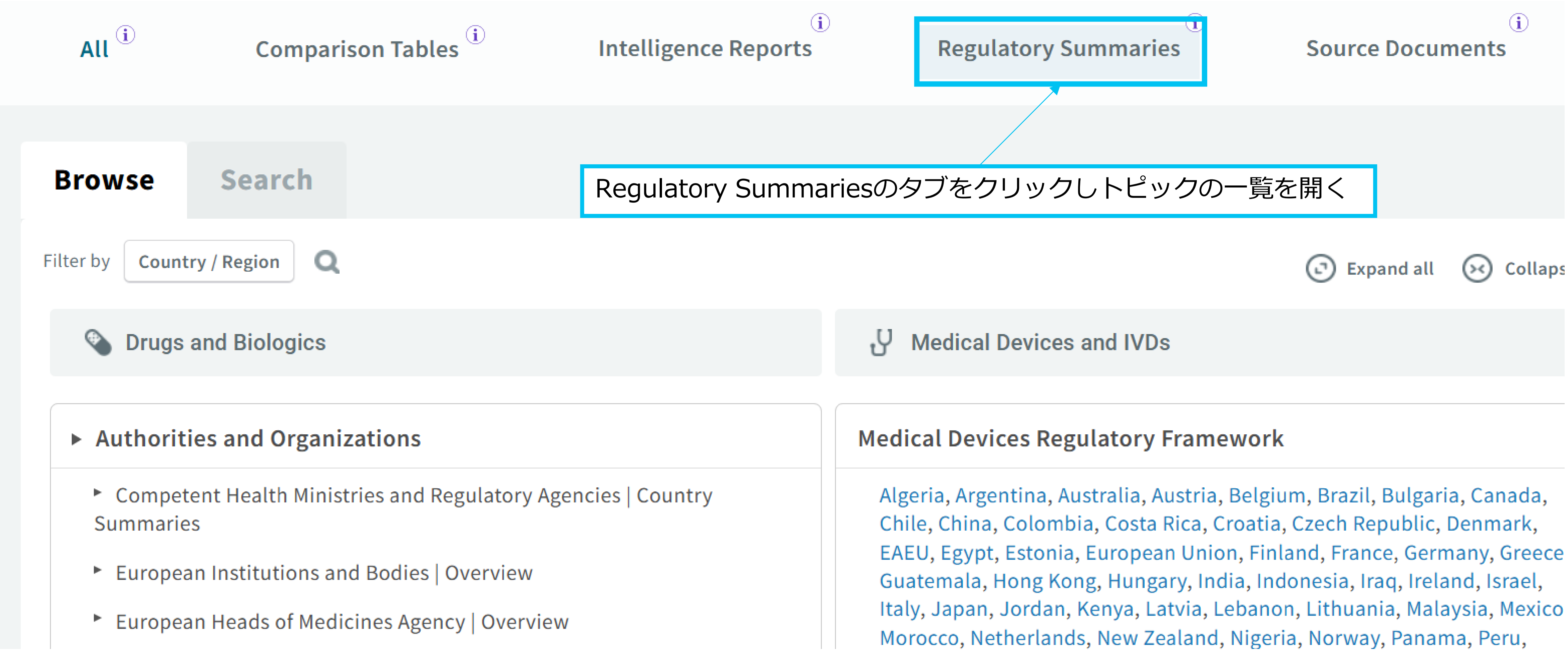
Regulatory Summariesへのアクセス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Drugs and Biologics
Medical Devices and IVDs

Regulatory Summariesのタブをクリックしトピックの一覧を開く

Authorities and Organizations

- Competent Health Ministries and Regulatory Agencies | Country Summaries
- European Institutions and Bodies | Overview
- European Heads of Medicines Agency | Overview

Medical Devices Regulatory Framework

Algeria, Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Czech Republic, Denmark, EAEU, Egypt, Estonia, European Union, Finland, France, Germany, Greece Guatemala, Hong Kong, Hungary, India, Indonesia, Iraq, Ireland, Israel, Italy, Japan, Jordan, Kenya, Latvia, Lebanon, Lithuania, Malaysia, Mexico Morocco, Netherlands, New Zealand, Nigeria, Norway, Panama, Peru,

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薬事規制業務に必要な実用的なインサイト

Cortellis Regulatory Intelligenceの付加価値コンテンツ

Source Documents

- 世界各国の規制当局・機関の公式文書
- 最新および過去バージョンを蓄積（バージョン管理情報付与）
- 全ての規制文書に英語のタイトル・抄録・更新理由等付加
- 現地語文書に機械翻訳を付与
- さらに一部の国は専門家による全文英訳を追加
- Medical Devices & IVDs: 16カ国
  China, South Korea, Taiwan, Japan,
  Brazil, Mexico, Israel, Russia,
  Argentina, Austria, France, Germany,
  Italy, Spain, Switzerland, Turkey

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- 随時更新

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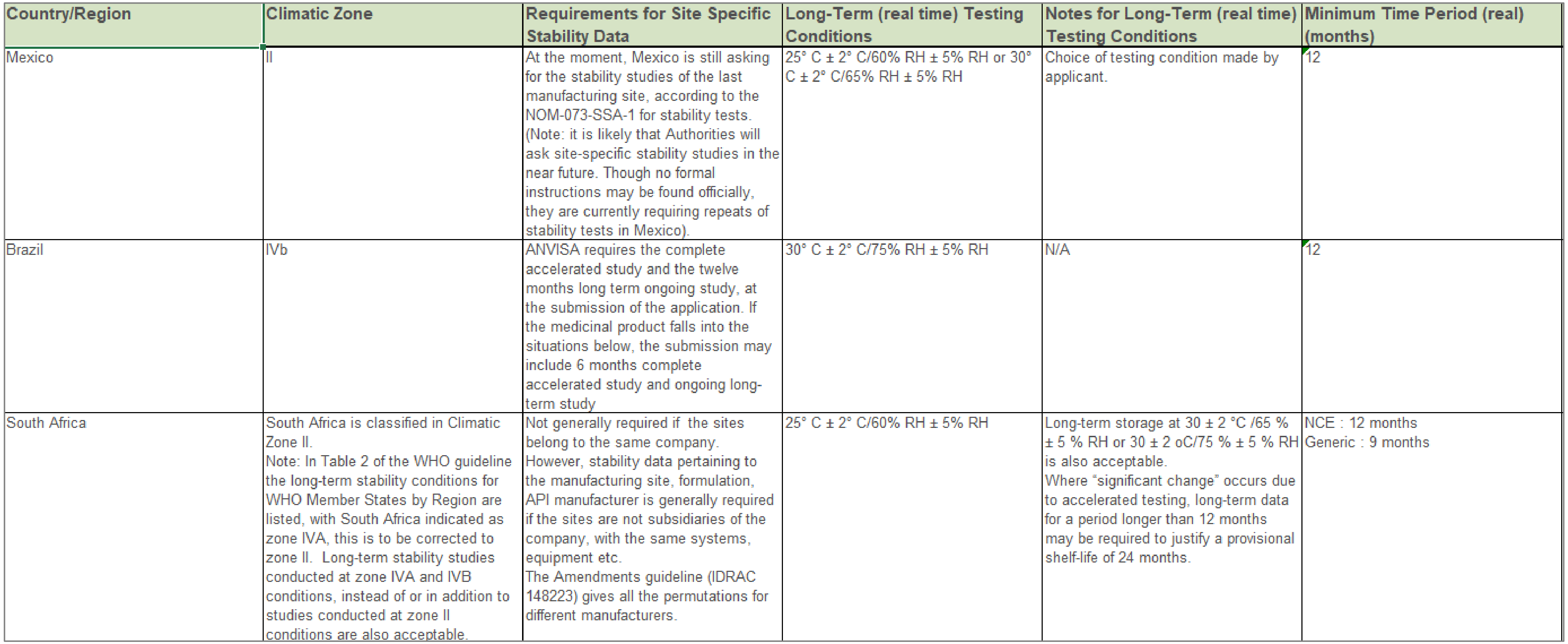
コンテンツ例

複数国の規制要件の比較分析

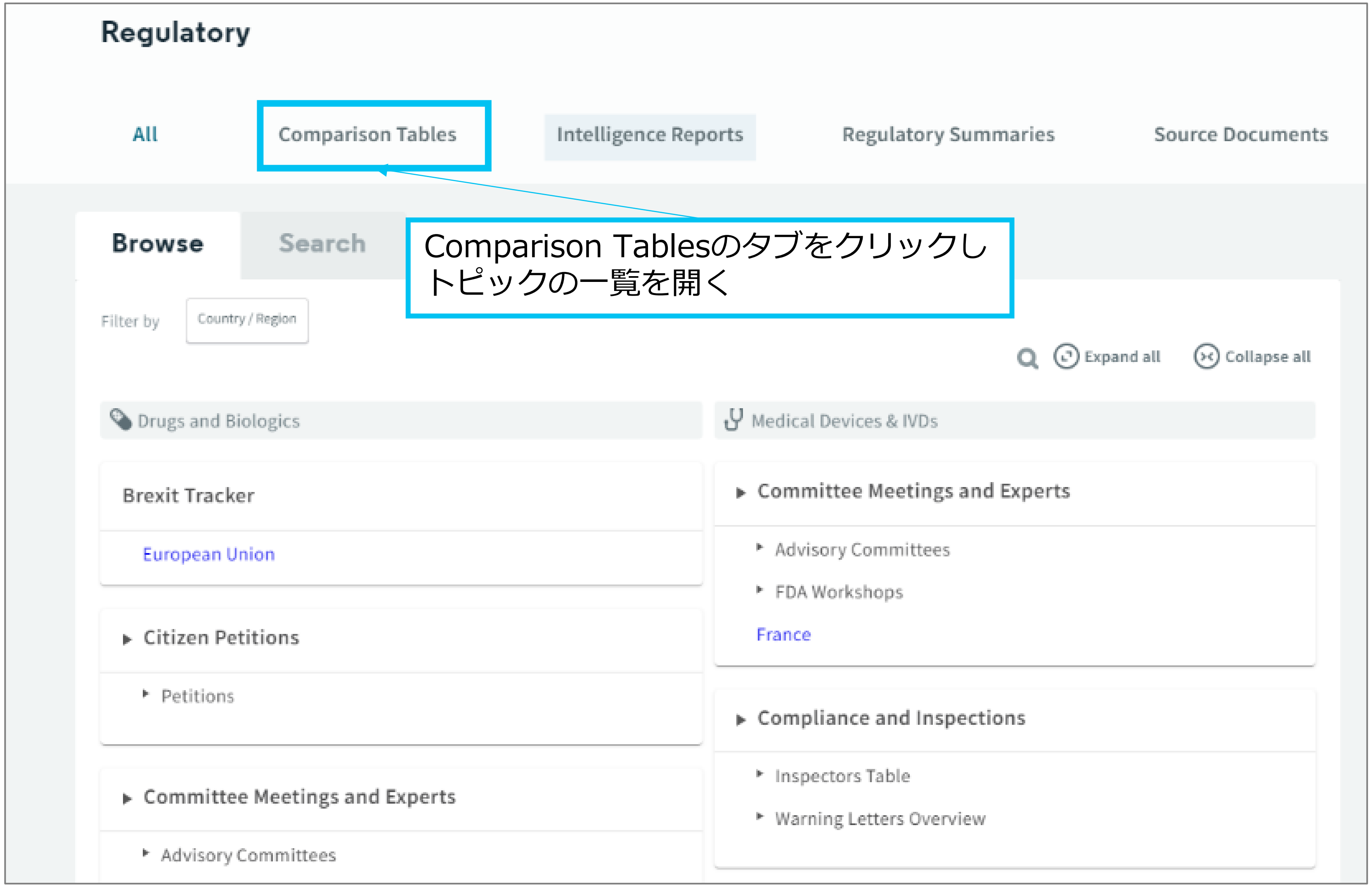
Comparison Tablesでは医薬品関連規制25種類の比較表を用意し随時アップデート

例：各国の安定性試験要件の比較表



Country/Region	Climatic Zone	Requirements for Site Specific Stability Data	Long-Term (real time) Testing Conditions	Notes for Long-Term (real time) Testing Conditions	Minimum Time Period (real) (months)
Mexico	II	At the moment, Mexico is still asking for the stability studies of the last manufacturing site, according to the NOM-073-SSA-1 for stability tests. (Note: it is likely that Authorities will ask site-specific stability studies in the near future. Though no formal instructions may be found officially, they are currently requiring repeats of stability tests in Mexico).	25° C ± 2° C/60% RH ± 5% RH or 30° C ± 2° C/65% RH ± 5% RH	Choice of testing condition made by applicant.	12
Brazil	IVb	ANVISA requires the complete accelerated study and the twelve months long term ongoing study, at the submission of the application. If the medicinal product falls into the situations below, the submission may include 6 months complete accelerated study and ongoing long-term study	30° C ± 2° C/75% RH ± 5% RH	N/A	12
South Africa	South Africa is classified in Climatic Zone II. Note: In Table 2 of the WHO guideline the long-term stability conditions for WHO Member States by Region are listed, with South Africa indicated as zone IVA, this is to be corrected to zone II. Long-term stability studies conducted at zone IVA and IVB conditions, instead of or in addition to studies conducted at zone II conditions are also acceptable.	Not generally required if the sites belong to the same company. However, stability data pertaining to the manufacturing site, formulation, API manufacturer is generally required if the sites are not subsidiaries of the company, with the same systems, equipment etc. The Amendments guideline (IDRAC 148223) gives all the permutations for different manufacturers.	25° C ± 2° C/60% RH ± 5% RH	Long-term storage at 30 ± 2 °C /65 % ± 5 % RH or 30 ± 2 oC/75 % ± 5 % RH is also acceptable. Where "significant change" occurs due to accelerated testing, long-term data for a period longer than 12 months may be required to justify a provisional shelf-life of 24 months.	NCE : 12 months Generic : 9 months

Comparison Tablesへのアクセス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Advisory Committees
Committee Meetings and Experts
Advisory Committees
FDA Workshops
France
Compliance and Inspections
Inspectors Table
Warning Letters Overview

Comparison Tablesのタブをクリックし
トピックの一覧を開く

ユーザーサポートのご案内

Support のご活用

ログイン後に画面端に表示される「Support」アイコンから様々なガイドをご利用頂けます。

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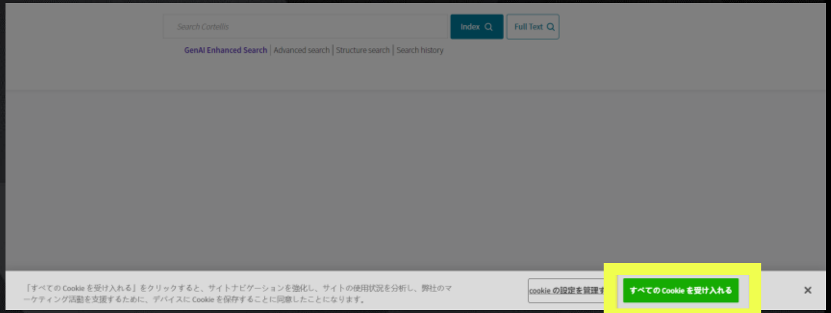
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- アップデートのお知らせ
- 使い方ガイド

（日本語あり）

- 各種トレーニング資料（日本語ページへのリンクあり）
- ユーザーコミュニケーションツールによるフィードバック

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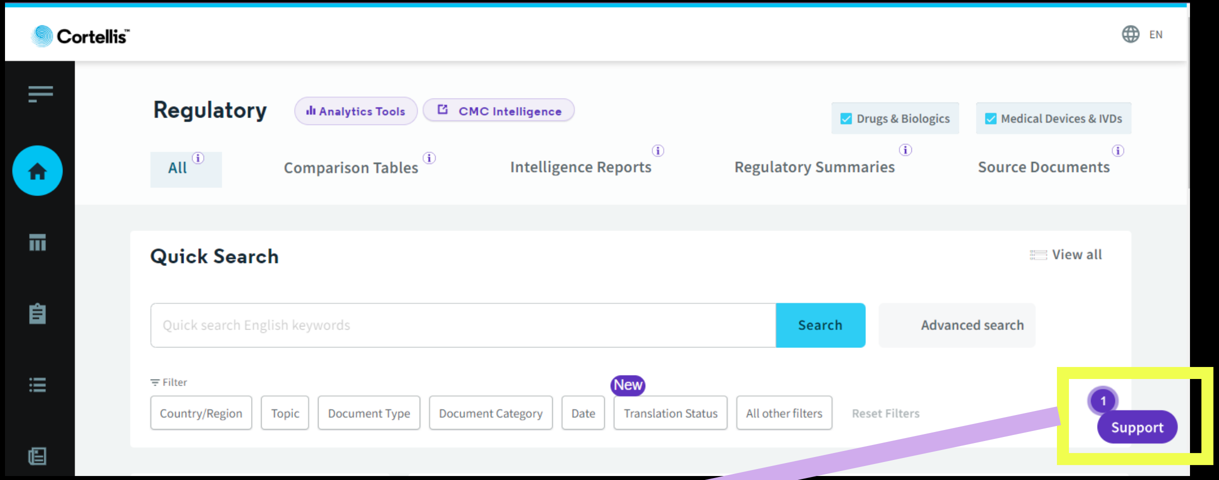
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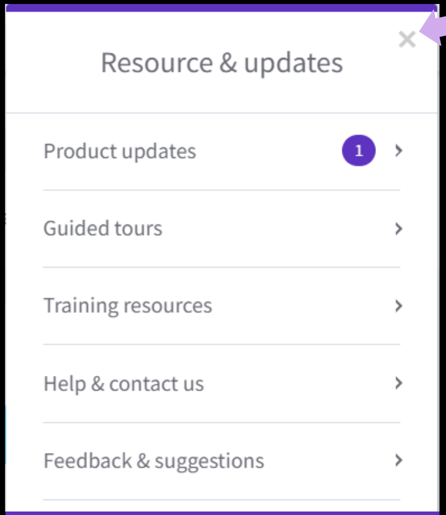
Document Category
Date
Translation Status
All other filters
Reset Filters
1
Support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Product updates
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Guided tours
Training resources
Help & contact us
Feedback & suggestions

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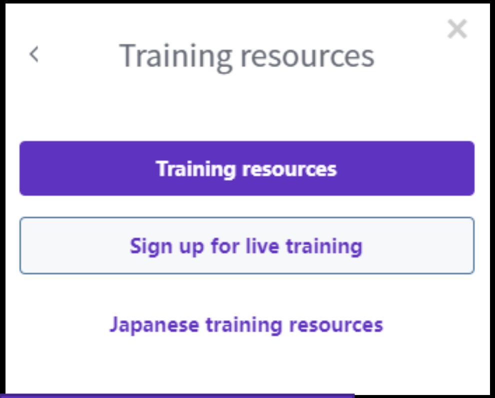
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Training resources
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Japanese training resources

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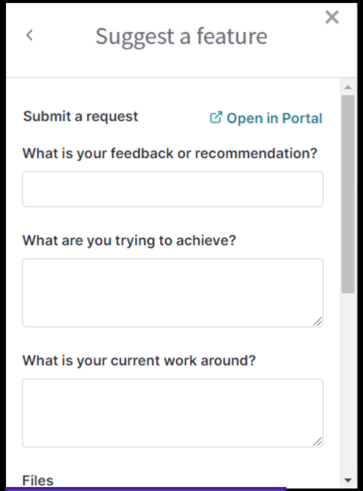
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What is your current work around?

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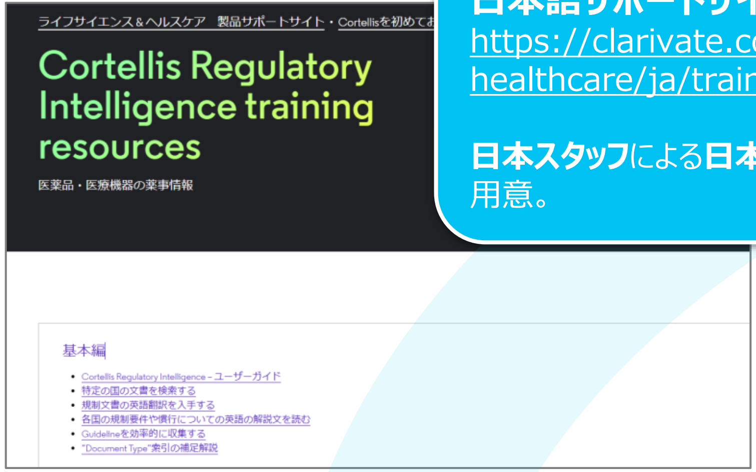

ライフサイエンス＆ヘルスケア　製品サポートサイト・Cortellisを初めてお

Cortellis Regulatory Intelligence training resources

医薬品・医療機器の薬事情報

基本編

- Cortellis Regulatory Intelligence – ユーザーガイド
- 特定の国の文書を検索する
- 規制文書の英語翻訳を入手する
- 各国の規制要件や慣行についての英語の解説文を読む
- Guidelineを効率的に収集する
- "Document Type"索引の補足解説

日本語サポートサイト
https://clarivate.com/life-sciences-healthcare/ja/training-support/

日本スタッフによる**日本語マニュアル・資料**をご用意。

パブリックWebセミナー
https://clarivate.com/life-sciences-healthcare/ja/training-support/training-calendar/
ユーザ様なら**どなたでも**参加できる**Webセミナー**を**年間を通じて**開催。参加できなくても**録画版を視聴**できます。

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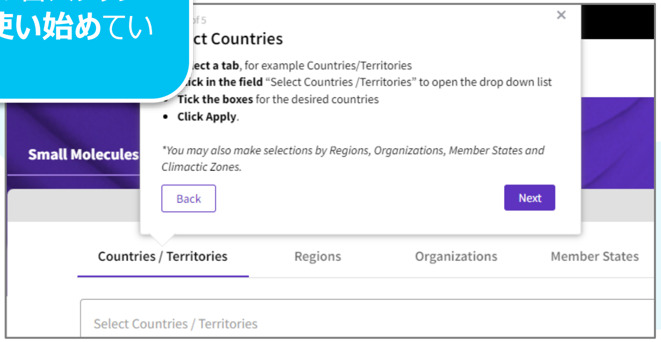
専門スタッフが対応。使い方、アクセスなどにお困りの際は、気軽に**日本語**で**問合せ**が可能。

製品内ガイドツアー

データベースの基本ワークフローの各ステップを解説するツアーで**スムーズに使い始め**ていただけます。



of 5

ct Countries

- **ect a tab**, for example Countries/Territories
- **ick in the field** "Select Countries /Territories" to open the drop down list
- **Tick the boxes** for the desired countries
- **Click Apply**.

**You may also make selections by Regions, Organizations, Member States and Climactic Zones.*

Ask the Expert

各製品で提供するコンテンツや分析結果について直接アナリストに問合せしていただけます。

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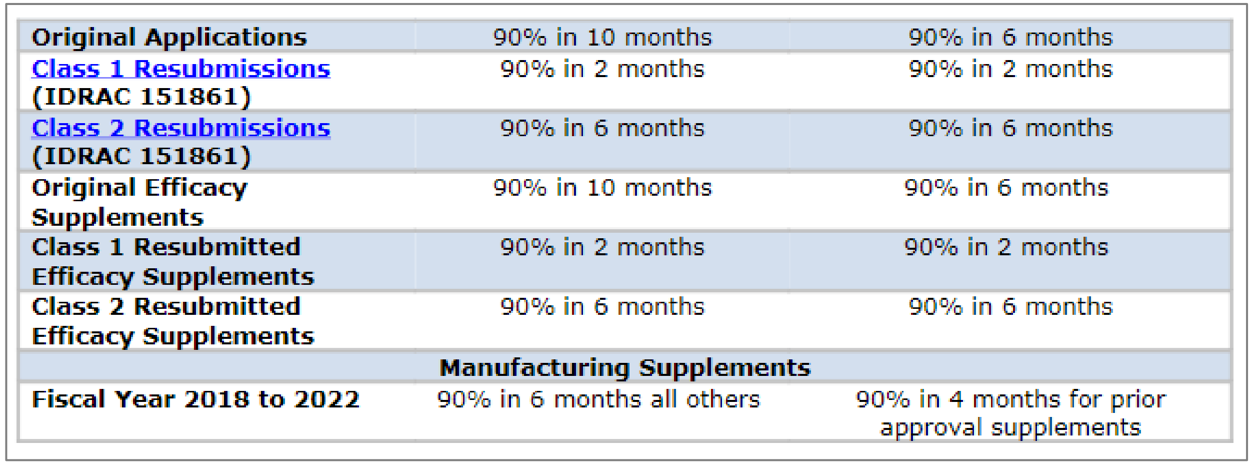
Appendix 1
業務別の活用事例

開発薬事業務の利用例

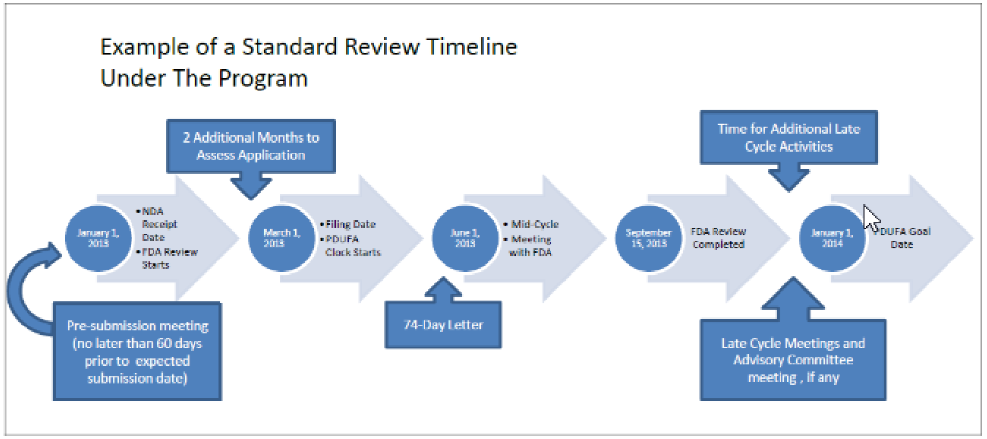
- 各国の申請要件、審査プロセスや承認までのタイムラインが異なる中で申請戦略を最適化
- 申請書の作成～提出～承認までの時間短縮を図る

利用例

- 特定の国の医薬品申請要件、ICHフォーマットとの違いを把握する
- 各国規制当局との事前相談制度や、承認までの標準的なタイムラインなど、審査プロセスの全体像を把握する
- 競合医薬品の先行事例を分析し、自社品の申請戦略に活かす



Original Applications	90% in 10 months	90% in 6 months
Class 1 Resubmissions (IDRAC 151861)	90% in 2 months	90% in 2 months
Class 2 Resubmissions (IDRAC 151861)	90% in 6 months	90% in 6 months
Original Efficacy Supplements	90% in 10 months	90% in 6 months
Class 1 Resubmitted Efficacy Supplements	90% in 2 months	90% in 2 months
Class 2 Resubmitted Efficacy Supplements	90% in 6 months	90% in 6 months
	Manufacturing Supplements	
Fiscal Year 2018 to 2022	90% in 6 months all others	90% in 4 months for prior approval supplements


Example of a Standard Review Timeline
Under The Program
2 Additional Months to Assess Application
Time for Additional Late Cycle Activities
January 1, 2013
• NDA Receipt Date
• FDA Review Starts
March 1, 2013
• Filing Date
• PDUFA Clock Starts
June 1, 2013
• Mid-Cycle
• Meeting with FDA
September 15, 2013
FDA Review Completed
January 1, 2014
PDUFA Goal Date
Pre-submission meeting (no later than 60 days prior to expected submission date)
74-Day Letter
Late Cycle Meetings and Advisory Committee meeting , If any

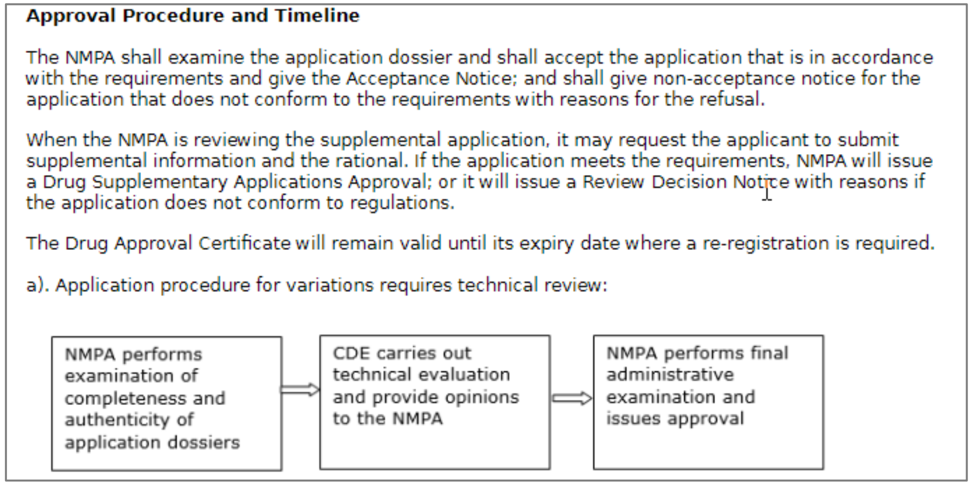
The Guidance for Review Staff and Industry (IDRAC 49531): Good Review Management Principles (2005) and Practices notes that FDA staff should establish and observe internal review timelines to help ensure efficiency and consistency in the review process. Practical aspects of product review, such as timelines for many elements of first cycle review, are in part established by PDUFA, however

CMC薬事業務の利用例

- 医薬品の各種承認申請手続きや審査プロセス調査
- GMP要件の把握、適合性調査対応の情報収集
- CMC対応にかかわる最新の通知やガイダンスの入手 etc.

利用例

- 特定の医薬品新規申請要件の調査や、CTDと現地フォーマットの差異を分析する
- DMF登録制度、ホルダー要件、申請手続きを調査する
- 生物学的同等性試験に関する各国の規制を収集する
- 複数の国の安定性試験の条件をまとめて把握し、要件の変更をモニタリングする
- 各国のGMP要件の把握と規制変更の最新情報を入手する



Approval Procedure and Timeline

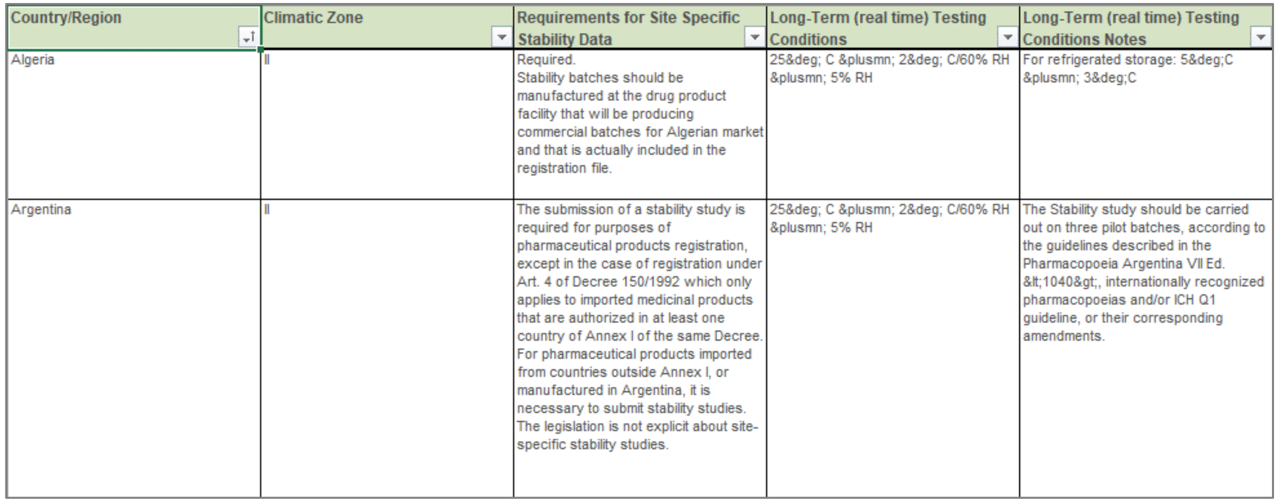
The NMPA shall examine the application dossier and shall accept the application that is in accordance with the requirements and give the Acceptance Notice; and shall give non-acceptance notice for the application that does not conform to the requirements with reasons for the refusal.

When the NMPA is reviewing the supplemental application, it may request the applicant to submit supplemental information and the rational. If the application meets the requirements, NMPA will issue a Drug Supplementary Applications Approval; or it will issue a Review Decision Notice with reasons if the application does not conform to regulations.

The Drug Approval Certificate will remain valid until its expiry date where a re-registration is required.

a). Application procedure for variations requires technical review:

NMPA performs examination of completeness and authenticity of application dossiers ⇒ CDE carries out technical evaluation and provide opinions to the NMPA ⇒ NMPA performs final administrative examination and issues approval



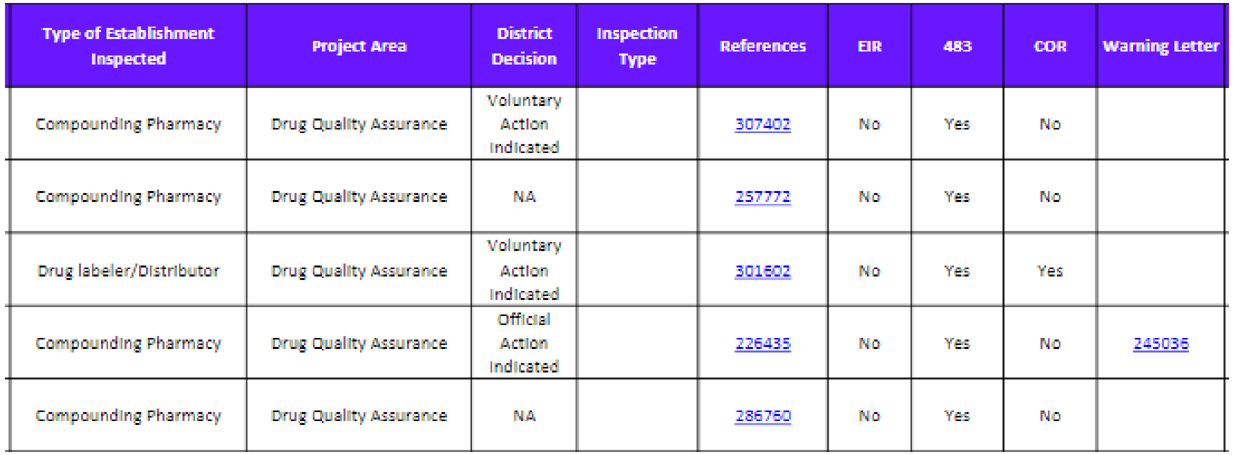
Country/Region	Climatic Zone	Requirements for Site Specific Stability Data	Long-Term (real time) Testing Conditions	Long-Term (real time) Testing Conditions Notes
Algeria	II	Required. Stability batches should be manufactured at the drug product facility that will be producing commercial batches for Algerian market and that is actually included in the registration file.	25&deg; C &plusmn; 2&deg; C/60% RH &plusmn; 5% RH	For refrigerated storage: 5&deg;C &plusmn; 3&deg;C
Argentina	II	The submission of a stability study is required for purposes of pharmaceutical products registration, except in the case of registration under Art. 4 of Decree 150/1992 which only applies to imported medicinal products that are authorized in at least one country of Annex I of the same Decree. For pharmaceutical products imported from countries outside Annex I, or manufactured in Argentina, it is necessary to submit stability studies. The legislation is not explicit about site-specific stability studies.	25&deg; C &plusmn; 2&deg; C/60% RH &plusmn; 5% RH	The Stability study should be carried out on three pilot batches, according to the guidelines described in the Pharmacopoeia Argentina VII Ed. <1040>, internationally recognized pharmacopoeias and/or ICH Q1 guideline, or their corresponding amendments.

製造・品質管理業務の利用例

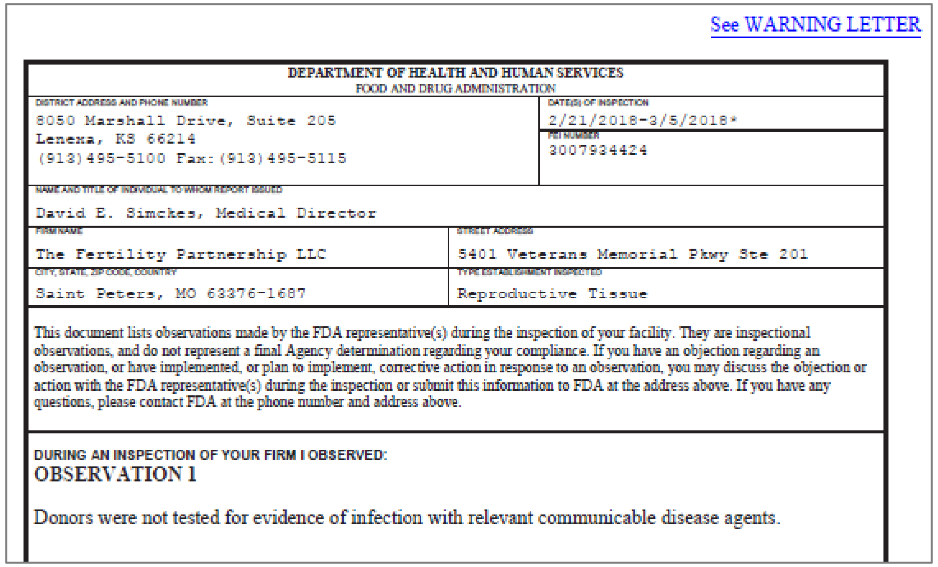
- 各国GXP最新ガイドラインの入手/GL変更の監視
- ICH品質ガイドラインのモニタリング
- GXP適合業務関連規制やFDA査察の事例分析

利用例

- 各国のGMPやGDP等の要件の把握と規制変更の最新情報を入手する
- 国内外の製造所の登録要件やライセンス更新の手続きなどを確認する
- 特定のFDA査察官の過去の査察の傾向を分析する
- 他社のFDA査察事例について、FDAウェブサイトで非公開のEIRやForm483も含めて入手する



Type of Establishment Inspected	Project Area	District Decision	Inspection Type	References	EIR	483	COR	Warning Letter
Compounding Pharmacy	Drug Quality Assurance	Voluntary Action Indicated		307402	No	Yes	No	
Compounding Pharmacy	Drug Quality Assurance	NA		257772	No	Yes	No	
Drug labeler/Distributor	Drug Quality Assurance	Voluntary Action Indicated		301602	No	Yes	Yes	
Compounding Pharmacy	Drug Quality Assurance	Official Action Indicated		226435	No	Yes	No	245036
Compounding Pharmacy	Drug Quality Assurance	NA		286760	No	Yes	No	



See WARNING LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER
8050 Marshall Drive, Suite 205
Lenexa, KS 66214
(913)495-5100 Fax:(913)495-5115

DATE(S) OF INSPECTION
2/21/2018-3/5/2018*

FEI NUMBER
3007934424

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David E. Simckes, Medical Director

FIRM NAME
The Fertility Partnership LLC

STREET ADDRESS
5401 Veterans Memorial Pkwy Ste 201

CITY, STATE, ZIP CODE, COUNTRY
Saint Peters, MO 63376-1687

TYPE ESTABLISHMENT INSPECTED
Reproductive Tissue

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

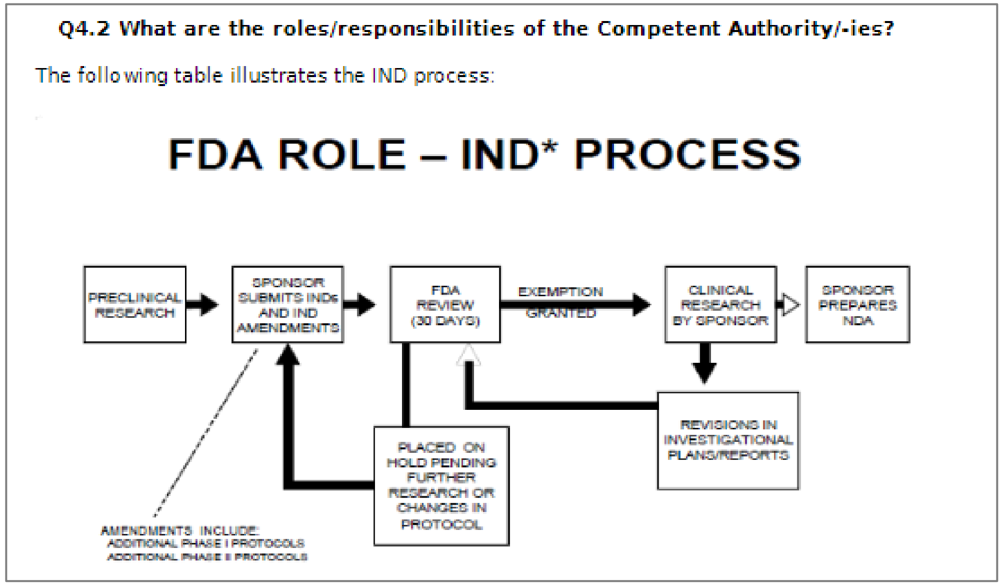
Donors were not tested for evidence of infection with relevant communicable disease agents.

臨床開発業務の利用例

- 各国の臨床試験実施要件の把握や、各国間の要件比較
- 各国の最新のGCPの確認や規制変更の追跡

利用例

- 治験実施申請、治験の実施運営に関わる様々な規制、手続きプロセスを確認する
- 各国の臨床試験におけるリアルワールドデータの活用に関するガイダンスを確認する
- 当局との治験事前相談制度の有無、相談手続き方法を調べる
- 臨床試験実施要件の各国比較

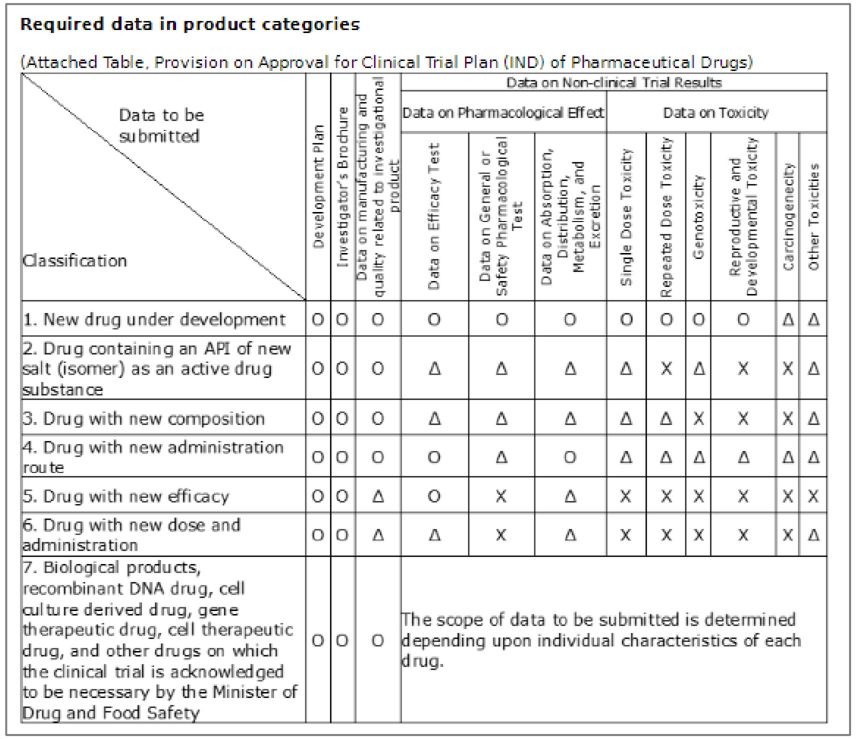


Q4.2 What are the roles/responsibilities of the Competent Authority/-ies?

The following table illustrates the IND process:

FDA ROLE – IND* PROCESS

PRECLINICAL RESEARCH
SPONSOR SUBMITS INDs AND IND AMENDMENTS
FDA REVIEW (30 DAYS)
EXEMPTION GRANTED
CLINICAL RESEARCH BY SPONSOR
SPONSOR PREPARES NDA
PLACED ON HOLD PENDING FURTHER RESEARCH OR CHANGES IN PROTOCOL
REVISIONS IN INVESTIGATIONAL PLANS/REPORTS
AMENDMENTS INCLUDE:
ADDITIONAL PHASE I PROTOCOLS
ADDITIONAL PHASE II PROTOCOLS



Required data in product categories

(Attached Table, Provision on Approval for Clinical Trial Plan (IND) of Pharmaceutical Drugs)

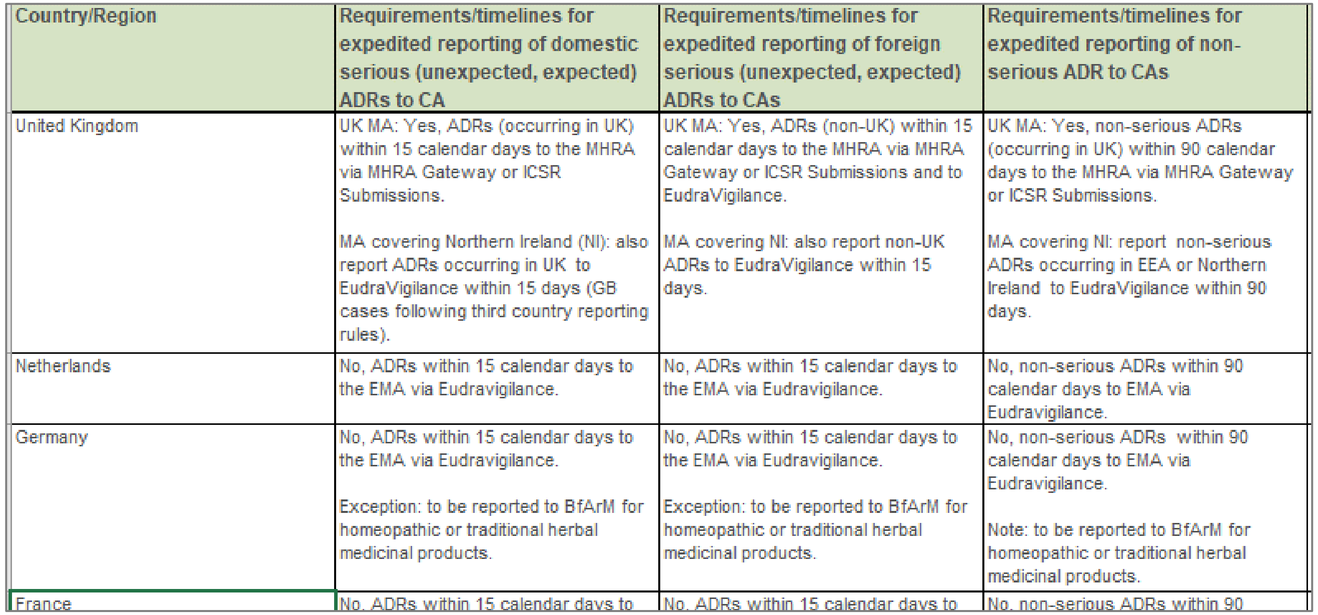
Data to be submitted Classification	Development Plan	Investigator's Brochure	Data on manufacturing and quality related to investigational product	Data on Non-clinical Trial Results								
				Data on Pharmacological Effect			Data on Toxicity					
				Data on Efficacy Test	Data on General or Safety Pharmacological Test	Data on Absorption, Distribution, Metabolism, and Excretion	Single Dose Toxicity	Repeated Dose Toxicity	Genotoxicity	Reproductive and Developmental Toxicity	Carcinogenecity	Other Toxicities
1. New drug under development	O	O	O	O	O	O	O	O	O	O	Δ	Δ
2. Drug containing an API of new salt (isomer) as an active drug substance	O	O	O	Δ	Δ	Δ	Δ	X	Δ	X	X	Δ
3. Drug with new composition	O	O	O	Δ	Δ	Δ	Δ	Δ	X	X	X	Δ
4. Drug with new administration route	O	O	O	O	Δ	O	Δ	Δ	Δ	Δ	Δ	Δ
5. Drug with new efficacy	O	O	Δ	O	X	Δ	X	X	X	X	X	X
6. Drug with new dose and administration	O	O	Δ	Δ	X	Δ	X	X	X	X	X	Δ
7. Biological products, recombinant DNA drug, cell culture derived drug, gene therapeutic drug, cell therapeutic drug, and other drugs on which the clinical trial is acknowledged to be necessary by the Minister of Drug and Food Safety	O	O	O	The scope of data to be submitted is determined depending upon individual characteristics of each drug.								

ファーマコビジランスの利用例

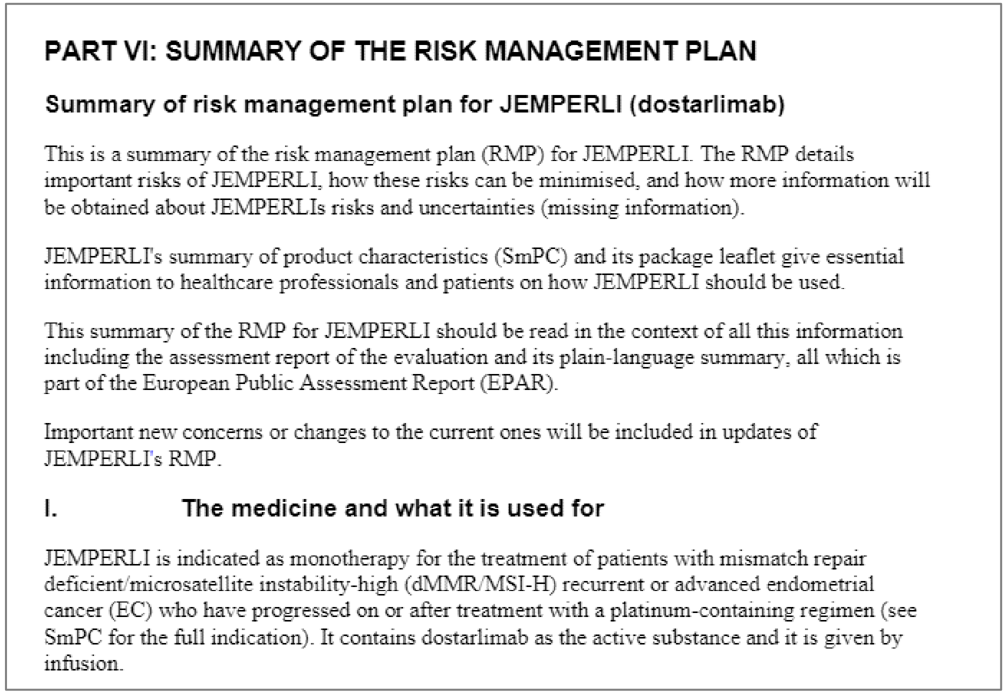
- 各国の開発中/市販後の安全性情報の報告要件を把握・比較する
- 競合品のリスク管理情報を分析する

利用例

- 各国のPV関連規制を網羅的に入手し、承認前後の安全性情報の報告基準を把握する
- 複数国の治験薬/市販後製品の安全性情報の報告期限を一覧比較し、要件変更をモニタリングする
- 競合製品の承認情報に紐づくリスク管理計画や添付文書情報を入手する



Country/Region	Requirements/timelines for expedited reporting of domestic serious (unexpected, expected) ADRs to CA	Requirements/timelines for expedited reporting of foreign serious (unexpected, expected) ADRs to CAs	Requirements/timelines for expedited reporting of non-serious ADR to CAs
United Kingdom	UK MA: Yes, ADRs (occurring in UK) within 15 calendar days to the MHRA via MHRA Gateway or ICSR Submissions. MA covering Northern Ireland (NI): also report ADRs occurring in UK to EudraVigilance within 15 days (GB cases following third country reporting rules).	UK MA: Yes, ADRs (non-UK) within 15 calendar days to the MHRA via MHRA Gateway or ICSR Submissions and to EudraVigilance. MA covering NI: also report non-UK ADRs to EudraVigilance within 15 days.	UK MA: Yes, non-serious ADRs (occurring in UK) within 90 calendar days to the MHRA via MHRA Gateway or ICSR Submissions. MA covering NI: report non-serious ADRs occurring in EEA or Northern Ireland to EudraVigilance within 90 days.
Netherlands	No, ADRs within 15 calendar days to the EMA via Eudravigilance.	No, ADRs within 15 calendar days to the EMA via Eudravigilance.	No, non-serious ADRs within 90 calendar days to EMA via Eudravigilance.
Germany	No, ADRs within 15 calendar days to the EMA via Eudravigilance. Exception: to be reported to BfArM for homeopathic or traditional herbal medicinal products.	No, ADRs within 15 calendar days to the EMA via Eudravigilance. Exception: to be reported to BfArM for homeopathic or traditional herbal medicinal products.	No, non-serious ADRs within 90 calendar days to EMA via Eudravigilance. Note: to be reported to BfArM for homeopathic or traditional herbal medicinal products.
France	No, ADRs within 15 calendar days to	No, ADRs within 15 calendar days to	No, non-serious ADRs within 90



PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for JEMPERLI (dostarlimab)

This is a summary of the risk management plan (RMP) for JEMPERLI. The RMP details important risks of JEMPERLI, how these risks can be minimised, and how more information will be obtained about JEMPERLIs risks and uncertainties (missing information).

JEMPERLI's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how JEMPERLI should be used.

This summary of the RMP for JEMPERLI should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of JEMPERLI's RMP.

I. The medicine and what it is used for

JEMPERLI is indicated as monotherapy for the treatment of patients with mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) recurrent or advanced endometrial cancer (EC) who have progressed on or after treatment with a platinum-containing regimen (see SmPC for the full indication). It contains dostarlimab as the active substance and it is given by infusion.

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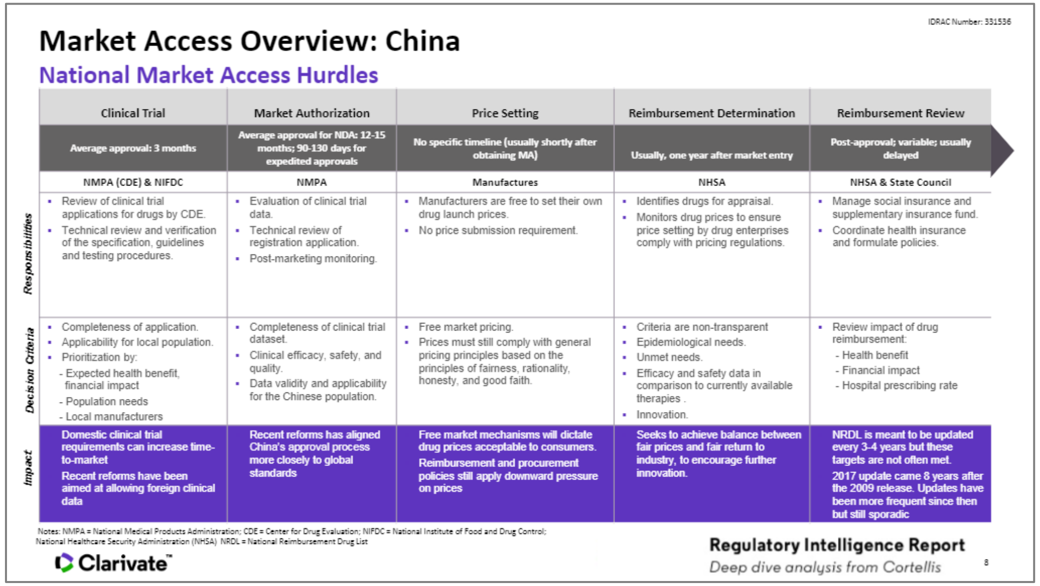
市場アクセス業務の利用例

- 各国の薬価、保険償還に関する制度や申請プロセスを理解する
- 各国の保険償還プロセスにおけるステークホルダーの理解を深める
- HTAの取入れ状況やHTA機関の要求事項を把握する

利用例

- 各国で異なる医療システム、薬価および保険償還制度など、市場アクセスの影響要因の全体像を把握する
- 薬価・保険償還決定、HTAのプロセスやタイムラインを把握する
- 保険償還の意思決定に影響を与えるキードライバーや、医療費抑制策などの市場アクセス障壁を分析する
- HTAの導入状況や、HTA機関による評価結果が保険償還にどれくらいの影響力を持っているのか把握する



IDRAC Number: 331536

Market Access Overview: China

National Market Access Hurdles

	Clinical Trial	Market Authorization	Price Setting	Reimbursement Determination	Reimbursement Review
	Average approval: 3 months	**Average approval for NDA: 12-15 months; 90-130 days for expedited approvals**	**No specific timeline (usually shortly after obtaining MA)**	**Usually, one year after market entry**	**Post-approval; variable; usually delayed**
	NMPA (CDE) & NIFDC	**NMPA**	**Manufactures**	**NHSA**	**NHSA & State Council**
Responsibilities	▪ Review of clinical trial applications for drugs by CDE. ▪ Technical review and verification of the specification, guidelines and testing procedures.	▪ Evaluation of clinical trial data. ▪ Technical review of registration application. ▪ Post-marketing monitoring.	▪ Manufacturers are free to set their own drug launch prices. ▪ No price submission requirement.	▪ Identifies drugs for appraisal. ▪ Monitors drug prices to ensure price setting by drug enterprises comply with pricing regulations.	▪ Manage social insurance and supplementary insurance fund. ▪ Coordinate health insurance and formulate policies.
Decision Criteria	▪ Completeness of application. ▪ Applicability for local population. ▪ Prioritization by: - Expected health benefit, financial impact - Population needs - Local manufacturers	▪ Completeness of clinical trial dataset. ▪ Clinical efficacy, safety, and quality. ▪ Data validity and applicability for the Chinese population.	▪ Free market pricing. ▪ Prices must still comply with general pricing principles based on the principles of fairness, rationality, honesty, and good faith.	▪ Criteria are non-transparent ▪ Epidemiological needs. ▪ Unmet needs. ▪ Efficacy and safety data in comparison to currently available therapies . ▪ Innovation.	▪ Review impact of drug reimbursement: - Health benefit - Financial impact - Hospital prescribing rate
Impact	**Domestic clinical trial requirements can increase time-to-market** **Recent reforms have been aimed at allowing foreign clinical data**	**Recent reforms has aligned China's approval process more closely to global standards**	**Free market mechanisms will dictate drug prices acceptable to consumers.** **Reimbursement and procurement policies still apply downward pressure on prices**	**Seeks to achieve balance between fair prices and fair return to industry, to encourage further innovation.**	**NRDL is meant to be updated every 3-4 years but these targets are not often met.** **2017 update came 8 years after the 2009 release. Updates have been more frequent since then but still sporadic**

Notes: NMPA = National Medical Products Administration; CDE = Center for Drug Evaluation; NIFDC = National Institute of Food and Drug Control; National Healthcare Security Administration (NHSA) NRDL = National Reimbursement Drug List

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Regulatory Intelligence Report
Deep dive analysis from Cortellis

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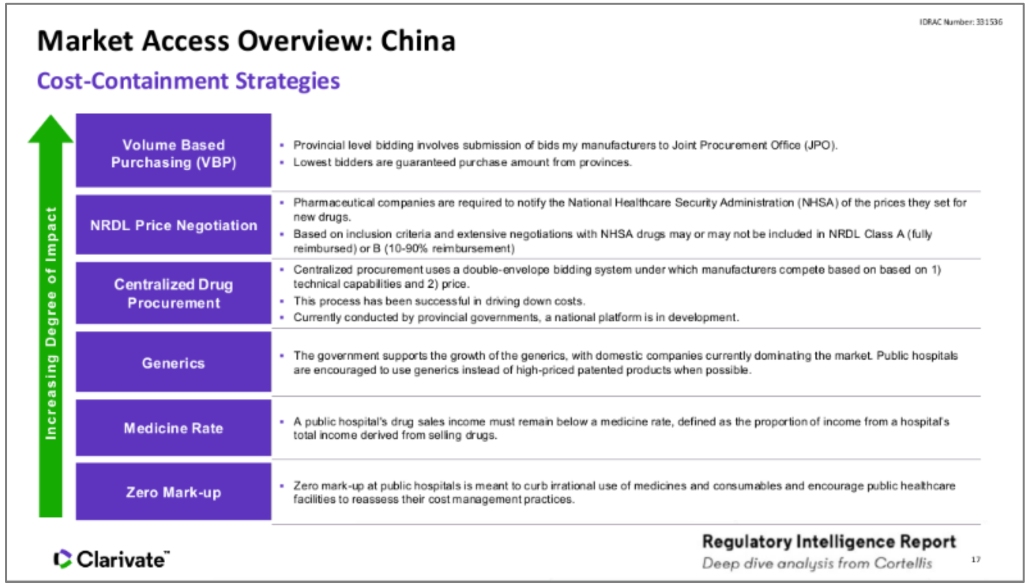

IDRAC Number: 331536

Market Access Overview: China

Cost-Containment Strategies

Volume Based Purchasing (VBP)	▪ Provincial level bidding involves submission of bids my manufacturers to Joint Procurement Office (JPO). ▪ Lowest bidders are guaranteed purchase amount from provinces.
NRDL Price Negotiation	▪ Pharmaceutical companies are required to notify the National Healthcare Security Administration (NHSA) of the prices they set for new drugs. ▪ Based on inclusion criteria and extensive negotiations with NHSA drugs may or may not be included in NRDL Class A (fully reimbursed) or B (10-90% reimbursement)
Centralized Drug Procurement	▪ Centralized procurement uses a double-envelope bidding system under which manufacturers compete based on based on 1) technical capabilities and 2) price. ▪ This process has been successful in driving down costs. ▪ Currently conducted by provincial governments, a national platform is in development.
Generics	▪ The government supports the growth of the generics, with domestic companies currently dominating the market. Public hospitals are encouraged to use generics instead of high-priced patented products when possible.
Medicine Rate	▪ A public hospital's drug sales income must remain below a medicine rate, defined as the proportion of income from a hospital's total income derived from selling drugs.
Zero Mark-up	▪ Zero mark-up at public hospitals is meant to curb irrational use of medicines and consumables and encourage public healthcare facilities to reassess their cost management practices.

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Deep dive analysis from Cortellis

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Appendix 2
規制分析コンテンツ トピック紹介

Regulatory Summaries（規制の解説文書）– Drugs & Biologics

Authorities and Organizations	医薬品・医療機器規制に関与する当局の情報
International and Regional Bodies	ICH, PIC/S, ASEANなどの国際組織の情報
Legal Definitions and Marketing Requirements	医薬品や医療機器の定義や分類
Prescription and Supply Requirements	処方薬の定義や流通に関する基本的な要件
Registration Application | Application Format, Content and Overview	医薬品申請書式、提出データ要件など
Registration Application | Submission Process Overview	申請方法や電子申請ファイルの取扱いなど
Marketing Authorization Procedures	審査プロセス、事前相談、製造販売業の認可、薬局方、スイッチOTC、優先審査制度、承認承継、未承認薬の使用、変更申請など
Fees Payable	各種申請費用
Labeling, Packaging and Product Information Requirements	添付文書、パッケージ、ラベルに関する要件など
Clinical Trial Regulatory Requirements	臨床試験実施プロセスや、治験薬の管理、ラベル、輸出入の要件など
Quality Assurance Requirements	GXP関連の要求事項など
Pharmacovigilance and Risk Management Regulatory Requirements	市販前/後の安全管理要件、ADE報告要件など
Import and Export Regulatory Requirements	輸出入関連規制、ライセンスなど
Advertising and Promotion Regulations	広告規制
Market Access Guidance	薬価算定、保険償還プロセス、HTA制度の解説
Pricing and Reimbursement System and Policy Overview	薬価制度、保険償還（上記Market Access Guidanceでカバーされない国の情報）
Environmental Assessment and Impact Guidance	環境関連規制
How to Market…	遺伝子治療、細胞治療、再生医療、コンビネーション製品、小児適応、後発品、漢方薬、オーファンドラッグなどに特化した規制情報の解説

Regulatory Intelligence Report（分析レポート） – Drugs & Biologics

Brexit Tracker	英国のEU離脱によって必要となる対応やその期限などの情報
FDA Citizen Petitions	FDAに提出された請願書の一覧と本文へのリンク
Committee Meeting Trackers and Expert Profiles	FDA諮問委員会、EMA Scientific Committeeなど専門家組織やミーティングの情報
European Procedure Fees Trackers	欧州（EU, EEU）における医薬品申請に係る費用の情報
Compliance and Inspection Trackers	査察官名、サイト、Form 483, Warning Letterなど査察関連情報を集約
Global Market Access Insights	HTA, 薬価算定プロセス、保険償還システムなど市場アクセスに関する情報
Regulatory Authority Guideline Overview	各国・地域のガイドラインの一覧、変更の追跡に役立つ資料
Legislative Trackers	米国CFRなど規制変更の追跡資料
Product Approval Information	競合品のNDA, BLAなど申請・承認情報、承認までの期間、リスク管理計画の情報や審査報告書の入手
Public Comments and Outcomes | Consultation Documents	ドラフトガイドライン、パブリックコメント内容、最終的な告示内容などの情報
Regulatory Authority | Structure and Document Classification Guide	各国規制当局から発出される文書の種類や法的拘束力など

Comparison Tables（規制の比較表）トピック一覧– Drugs & Biologics

Comparison Tables

- Authorities and Organizations
  - Health Ministry and Regulatory Agency Directory
- Legal Definitions and Marketing Requirements
  - Legislative/Regulatory Framework: Biosimilar Products
  - Legislative/Regulatory Framework: Generic Products
  - National Pharmaceutical Laws and Regulations Directory
  - National Pharmacopeia Directory
- Format and Content of Applications
  - CTD Acceptability Framework
  - Finished Product Stability Data Requirements
- Marketing Authorization Procedures
  - Change of Manufacturing Site Requirements：Finished Product
  - Expanded/Compassionate Access Requirements
  - Expected Authority Review Timelines: Market Authorization Approval
- Fees
  - Pre- and Post-Approval National Fees Directory
- Product Information
  - Package Labeling Requirements

Comparison Tables

- Clinical Research
  - Clinical Trial Application Research Requirements: Local Requirements
  - Expected Authority Review Timelines: Clinical Trial Application and Ethics Committee
  - Investigational Medicinal Product (IMP) Labeling Requirements
  - Legislative/Regulatory Framework: Clinical Trial Registries and Results Disclosure
- Quality Assurance
  - National Good Practices (GXP) Directory
- Market Access Guidance
  - Health Technology Assessment Overview
  - Pharmaceutical Pricing and Reimbursement
- Pharmacovigilance and Risk Management
  - Post-Marketing Expedited Reporting
  - Post-Marketing Periodic Reporting
  - Pre-Marketing Expedited Reporting
  - Pre-Marketing Periodic Reporting
  - Risk Management Submission Requirements and Qualified Person for Pharmacovigilance (QPPV) Guidance
- Import and Export
  - Certificate of Pharmaceutical Product (CPP) Overview

Medical Devices & IVDs

Regulatory Summaries]
（規制の解説文書）

Regulatory Summaries
Medical Devices Regulatory Framework
In Vitro Diagnostics Regulatory Framework
Combination Products Regulatory Framework
International Medical Device Regulators Forum (IMDRF)

Regulatory Intelligence Report
（分析レポート）

Regulatory Intelligence Reports

- Committee Meeting Trackers
  - FDA Advisory Committees
  - FDA Workshops
- Compliance and Inspection Trackers
  - FDA Inspection Report Directory
  - FDA Warning Letter Directory
- Legislative Trackers
  - US Federal Register | Regulatory Timetable
  - EU IVD 2017 Regulation Highlights
  - EU Medical Device 2017 Regulation Highlights
- Product Approval Information
  - Medical Device Registration | Submission and Approval Tracker
  - Combination Product Registration | Submission and Approval Tracker
- Product Approval Information
  - Combination Product Submission and Approval Overview
  - Medical Devices Submission and Approval Overview
- Public Comments and Outcomes | Consultation Documents

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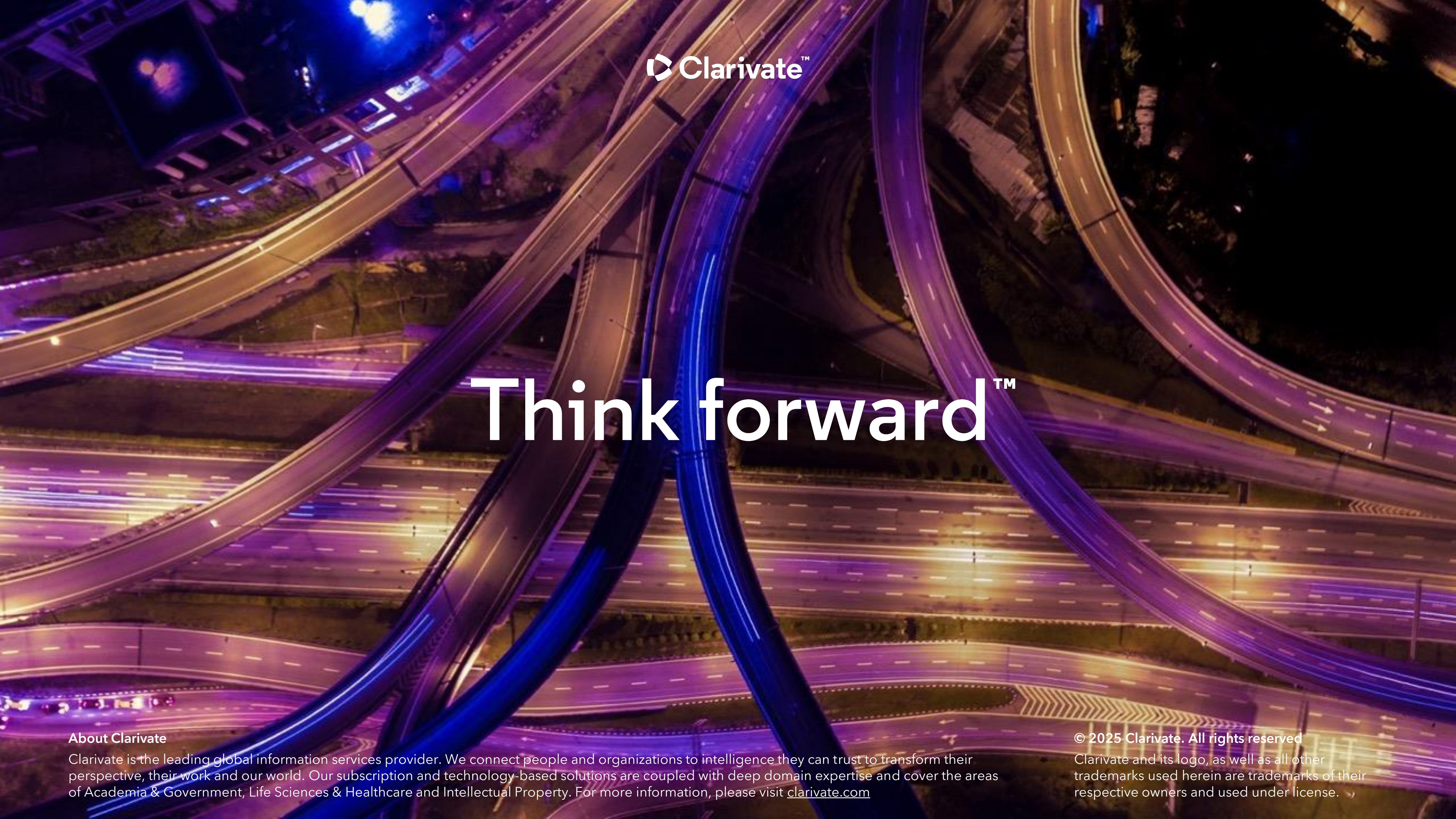
Medical Devices & IVDs
Comparison Tables（規制の比較表）

Comparison Tables

- Authorities and Organizations
  - IVD Regulatory Agency Directory
  - Medical Device Regulatory Agency Directory
- Legal Definitions and Product Classification
  - IVD Classification Summary
  - IVD Laws and Regulations Summary
  - Medical Device Classification Summary
  - Medical Device Laws and Regulations Summary
- Market Clearance
  - IVD Marketing Application Procedures
  - IVD Post-Marketing Procedures
  - Medical Device Marketing Application Procedures
  - Medical Device Post-Marketing Procedures

Comparison Tables

- Labeling and Promotion
  - IVD Labeling Requirements
  - Medical Device Advertising Requirements
  - Medical Device Labeling Requirements
- Quality Management System Requirements
  - IVD Quality Management System and Inspection Requirements
  - Medical Device Quality Management System and Inspection Requirements
- Market Surveillance
  - IVD Adverse Incident Reporting Requirements
  - Medical Device Adverse Incident Reporting Requirements
- Import and Export
  - Medical Device Import and Export Requirements



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