

Cortellis Regulatory Intelligence

基本編 – 世界の最新規制情報の収集と分析を
効率的に進めるには？

Cortellisパブリックウェブセミナー

Agenda

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

- 活用メリットと業務別の代表的な利用例

2. 新市場への進出に向けて 言語の壁を越えて、規制情報の収集・分析を効率的に進めるには？

- 各国規制の解説文、規制の比較表コンテンツの活用
- 関連規制文書（現地語＋英語）の取得

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できるWeekly Alertメール
- 規制のモニタリングに活用できるレポート例のご紹介
- 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”

4. 欲しい文書が探せなくて困っていませんか？ 強化された検索機能と各国規制エキスパートによるサポート

- 検索機能の操作方法と、アラート設定による新規文書、規制変更のモニタリング
- 現地語での規制文書検索に対応



Cortellis Regulatory Intelligence

データベース概要

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

各国規制情報を網羅的かつタイムリーに把握できていますか？



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

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

海外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

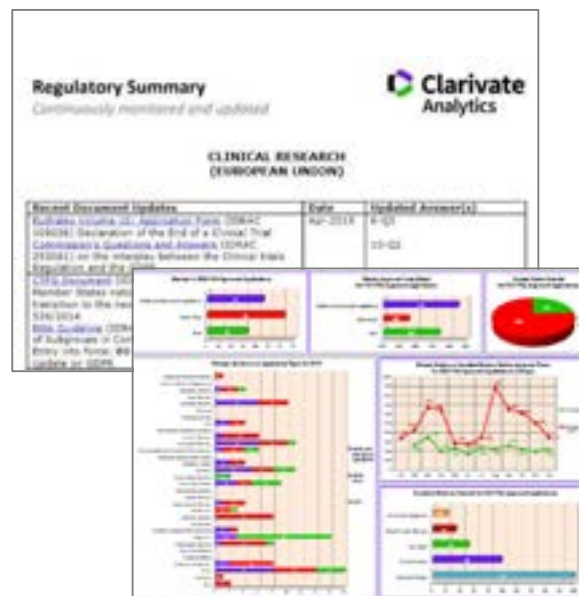
- 各国規制の英語での解説レポートや、
規制文書の英語翻訳を入手し、規制の理解を促進

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

Cortellis Regulatory Intelligence

- 医薬品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



81
国と地域



287K+
規制文書



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



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)

Cortellis Regulatory Intelligence利用事例の一部

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。

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。

複数の国での臨
床試験実施に
関する要件の全
体像を把握し、
関連ガイドライン
を効率的に収集
する。

治験薬・市販製
品の安全性情
報報告の要求
事項および報告
手続きを各国横
並びで比較する。

薬価・保険償還
制度や手続き
要件を調べる。
HTAの実態や
評価当局からの
要求事項を確認
する。

収録国一覧

81の国と地域

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)

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	Estonia	Ireland	Norway	Slovenia		
	Belgium	Finland	Italy	Poland	Spain		
	Bulgaria	France	Latvia	Portugal	Sweden		
	Croatia	Germany	Lithuania	Romania	Switzerland		
	Cyprus**	Greece	Luxembourg**	Russia	Turkey		
	Czech Republic	Hungary	Malta**	Serbia	Ukraine		
	Denmark	Iceland**	Netherlands	Slovakia	UK		
	Asia Pacific*	ASEAN					
		Australia	India	Malaysia	Singapore	Thailand	
China		Indonesia	New Zealand	South Korea	Vietnam		
Hong Kong		Japan	Philippines	Taiwan			
Latin America *	MERCOSUR		SICA**				
	Argentina	Chile	Costa Rica	Mexico	Peru		
	Brazil	Colombia	Guatemala	Panama	Venezuela		
Middle East, Africa*	GCC**						
	Algeria	Israel	Lebanon	Saudi Arabia	UAE		
	Egypt	Jordan	Morocco	South Africa			
	Iraq	Kenya	Nigeria	Tunisia			

収録コンテンツの4つのカテゴリ

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



Reference Documents (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
- Drugs & Biologics: 8か国
 - Medical Devices & IVDs: 16か国



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
 - ガイドライン一覧
 - FDA査察情報
 - 等



Comparison Tables

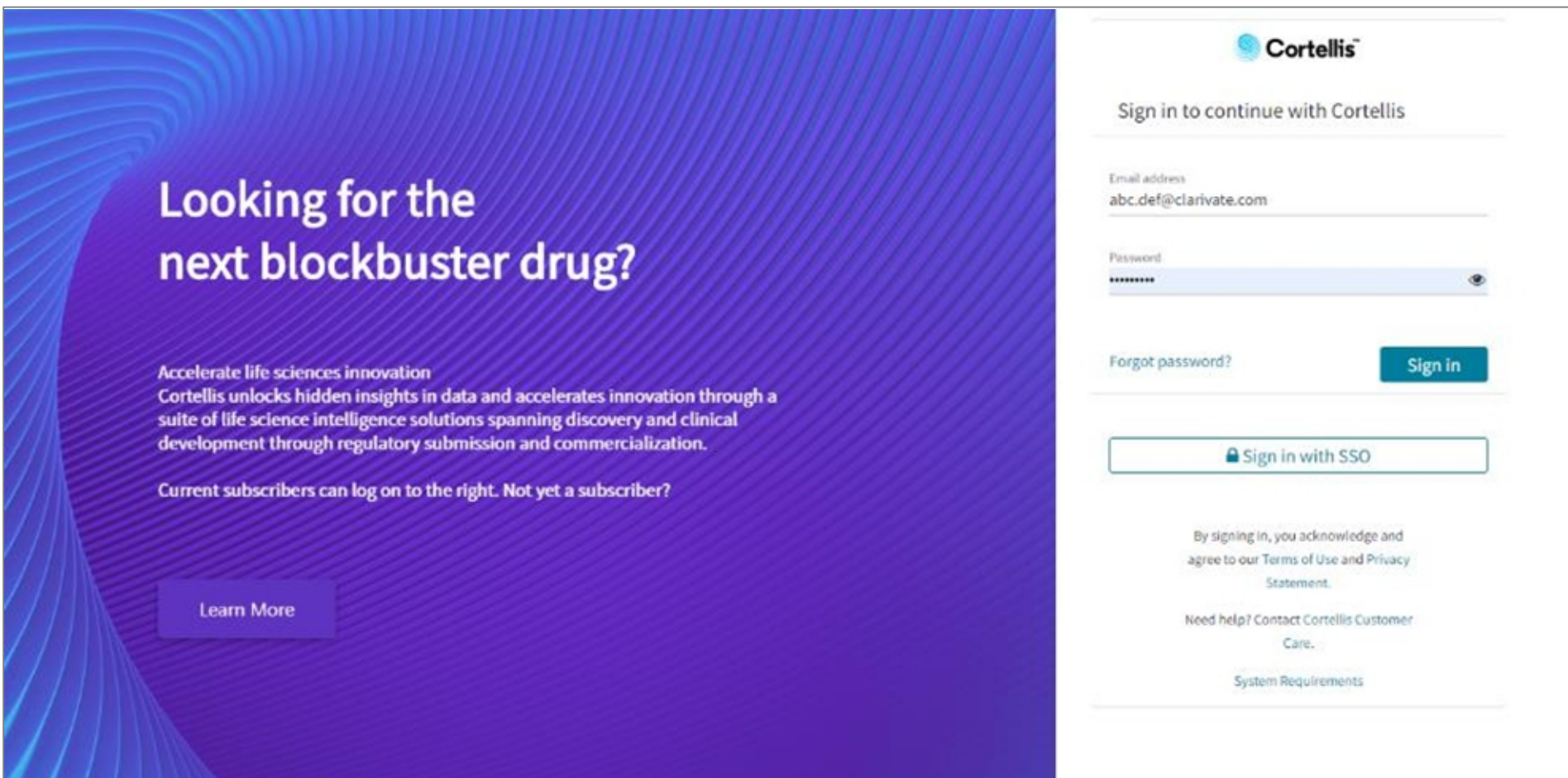
- 重要トピックに関する世界各国の規制比較表
- 規制の共通点・相違点を簡単に把握
- 主要な規制文書へのリンクで簡単に詳細を確認可能
- 随時更新



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?

[Learn More](#)

Cortellis™

Sign in to continue with Cortellis

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](#)

 Clarivate™ ※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

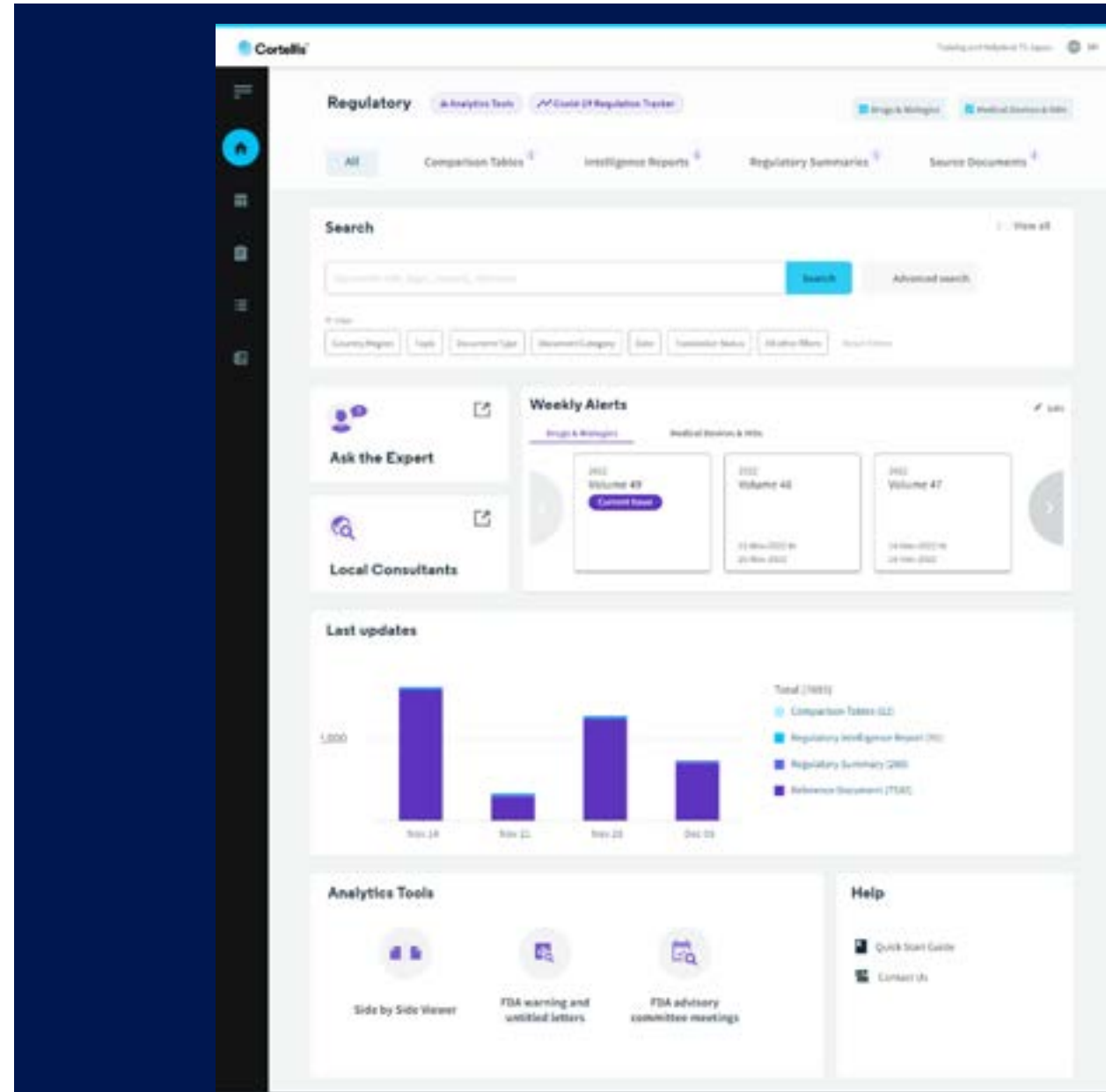
Cortellisにログインします



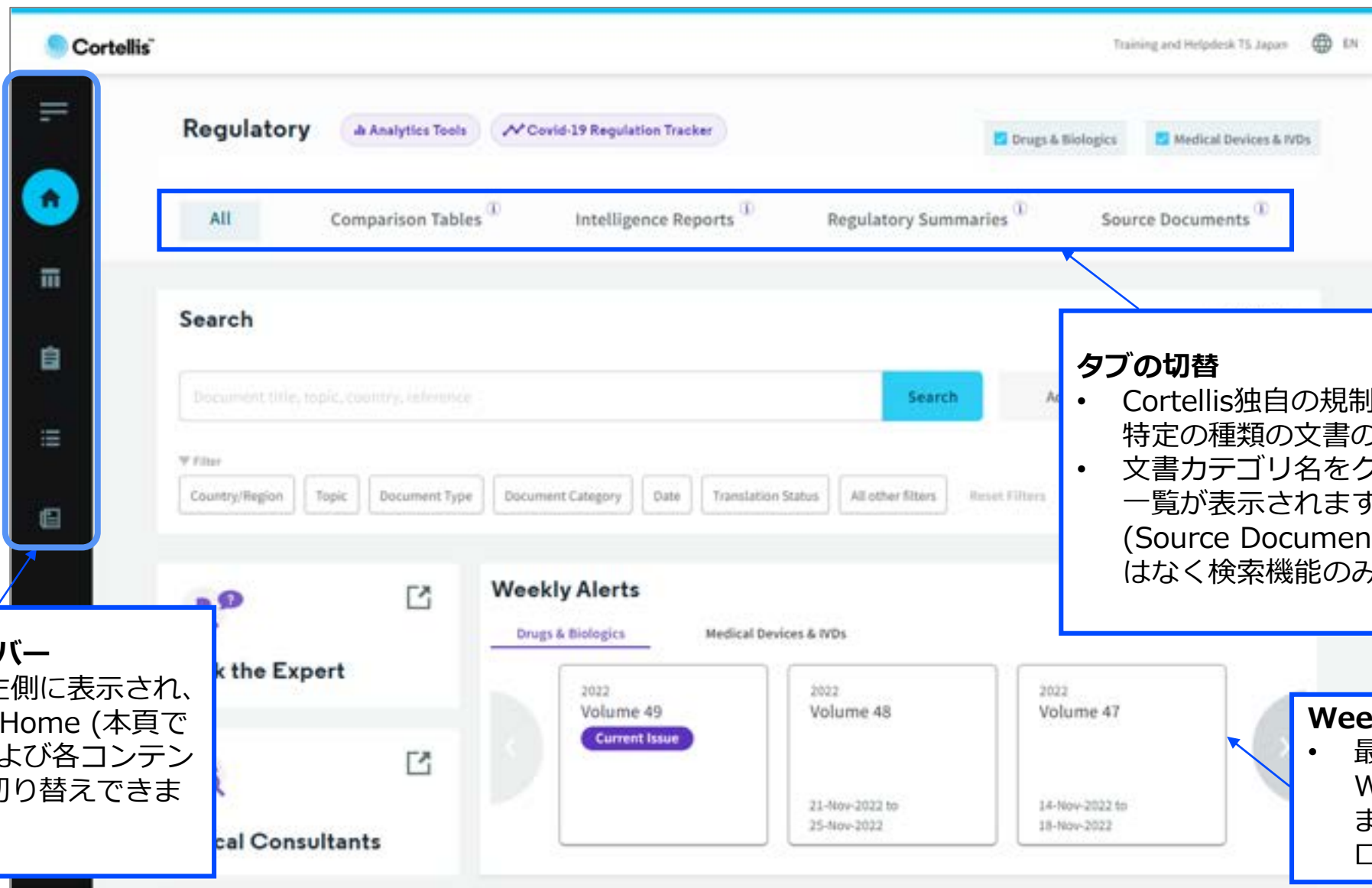
パネルが表示されていない場合は、“Regulatory Intelligence”の文字部分をクリックするとパネルが開きます

Cortellis Regulatory Intelligenceのホームページ

- Regulatory Intelligenceに特化したホームページが開きます



メインコンテンツへのアクセス



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

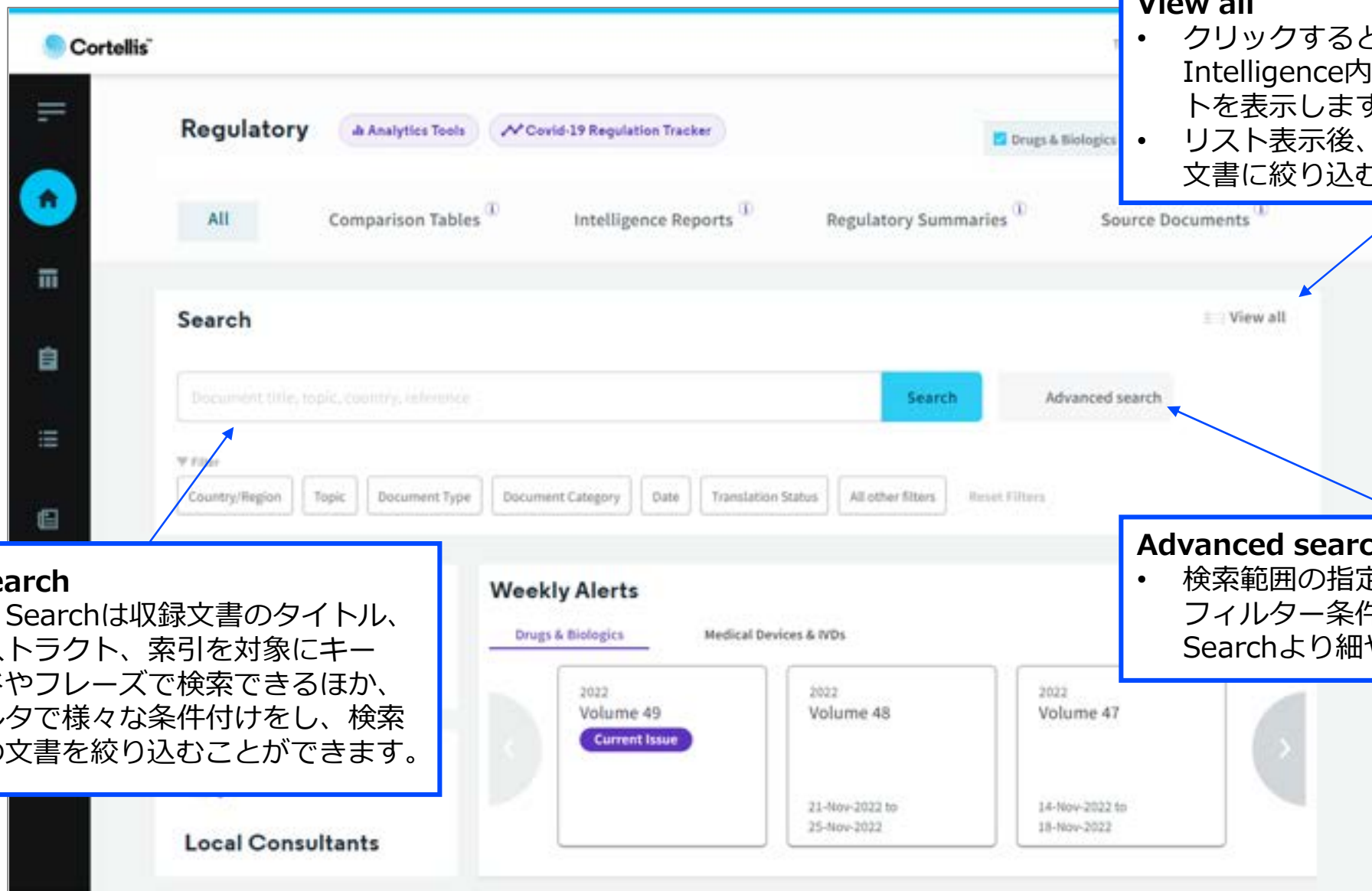
タブの切替

- 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)

Weekly Alerts

- 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

検索機能へのアクセス



View all

- クリックするとCortellis Regulatory Intelligence内の全ての収録文書の一覧を表示します。
- 一覧表示後、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. 新市場への進出に向けて 言語の壁を越えて、規制情報の収集・分析を 効率的に進めるには？

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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**は医薬品の開発段階～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 Legal Basis and Regulatory Framework
- Q2 Pre-Submission Phase
- Q3 Assessment of Marketing Authorization Applications
- Q4 Coming to Decisions
- Q5 Post-Authorization Phase
- Q6 Additional Information

Regulatory Summary

Continuously monitored and updated

Clarivate™

Marketing Authorization Procedures: Review, Communication and Approval (China)

Reason for update	Date	Reason for update description
Content Update	2021-03-26	CDE Notification No. 2021/21: Technical Requirements on Pharmaceutical Research and Evaluation of Chemical Drugs Already Marketed in Overseas but Not Yet Marketed in China (Trial, 03-Mar-2021 (IDRAC 326524), updated section Q6.2.
General Review	2021-02-02	Last update concern general information validation with minor change only.
Content Update	2021-01-28	NMPA Announcement No. 2020/145: Announcement on Drug Registration Online Submission, 25-Dec-2020 (IDRAC 323215), updated section Q6.1. Drug registration online submission function will be officially launched starting from 01-Jan-2021. Starting from 01-Apr-2021, the old form of drug registration submission will be not accepted any more.
Content Update	2021-01-06	CDE Notification No. 2020/48: Issuance of Provisions on Drug Development and Technical Review Communication, 10-Dec-2020 (IDRAC 322475); CDE Notification No. 2020/42: Issuance of CDE Working Procedures on Supplementary Dossier (Trial), 23-Nov-2020 (IDRAC 321700) and CDE Notification No. 2020/58: Issuance of Provisions on Drug Review and Approval Information Disclosure, 31-Dec-2020 (IDRAC 323385) updated section Q.2.3, Q3.4 and Q4.4.
Content Update	2020-12-07	CDE Notification No. 2020/41: Technical Guidance on Conditional Approval of Drugs (Interim), 19-Nov-2020 (IDRAC 321199), updated section Q6.1.
Content Update	2020-11-10	CDE Notification: Soliciting Public Comment on Provisions on Drug Review and Approval Information Disclosure (Draft), 27-Oct-2020 (IDRAC 320020), and Notification on Issuance of Approval Procedures and Submission Dossier Requirements for Drug Nomenclature, 01-Jul-2020 (IDRAC 320234), updated section Q4.4, Q6.1.

Review timeline are specified in [NMPA Order No. 27: Drug Registration Regulation, Revision, 22-Jan-2020](#) (IDRAC 308465). See table below.

	Common Process	Accelerated Process
Application for Clinical Trial Approval	60 calendar days	For Phase I Clinical trial, initiate technical review in 10 days after the priority review status is granted; for Phase II and III trials, initiate communication with sponsors in 30 days
Application for Marketing Authorization - standard (both ANDA and NDA)	200 working days	
Application for Marketing Authorization - Priority Review	130 working days	
Application for Marketing Authorization - Priority Review for orphan drug	70 working days	

The differences between common process and accelerated process are described in the Regulatory Summary [Priority Review/Accelerated Approval](#) (IDRAC 46794).

Q3.7 Is interaction with the competent authority (ies) during the review process possible? How should inquiries from the authority be handled? Is there any clock stop?

Providing Supplementary Information before Beginning of Assessment

After filing of application assembly, in principle NMPA doesn't accept that sponsor to provide additional information except for the New findings of drug safety.

Providing supplementary information before final decision

Supplementary information before final decision is mainly provided in accordance with the request/notification of NMPA or the CDE.

The applicant shall submit all supplementary materials as required at one time, and the time for supplementary materials shall not be included in the time limit for drug evaluation. The Drug Evaluation Center starts the evaluation after receiving all the supplementary information from the applicant, and the evaluation time limit is extended by 1/3; if the priority review and approval procedure is applied, the evaluation time limit is extended by 1/4.

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

規制の解説文のアクセス方法はこちら↓でも確認できます
CortellisクイックガイドNo.3 (Cortellisサポートサイトのリンク)

Regulatory Summariesへのアクセス

The screenshot displays the 'Regulatory' section of a website. At the top, there are five tabs: 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries' (highlighted with a blue box), and 'Source Documents'. Below the tabs, there are two main sections: 'Browse' and 'Search'. Under 'Browse', there is a 'Filter by' dropdown menu set to 'Country / Region'. Below this, there are two main categories: 'Drugs and Biologics' and 'Medical Devices & IVDs'. Under 'Medical Devices & IVDs', there is a section titled 'Medical Devices Regulatory Framework' which lists a long string of countries: Algeria, Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Czech Republic, Denmark, 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, Philippines, Poland, Portugal, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Tunisia, Turkey, USA, Ukraine, United Kingdom, Venezuela, Vietnam.

Regulatory Intelligenceホームページで
Regulatory Summariesのタブをクリック
しトピックの一覧を開く

各トピック項目内の国名を
クリックしてレポートを開く

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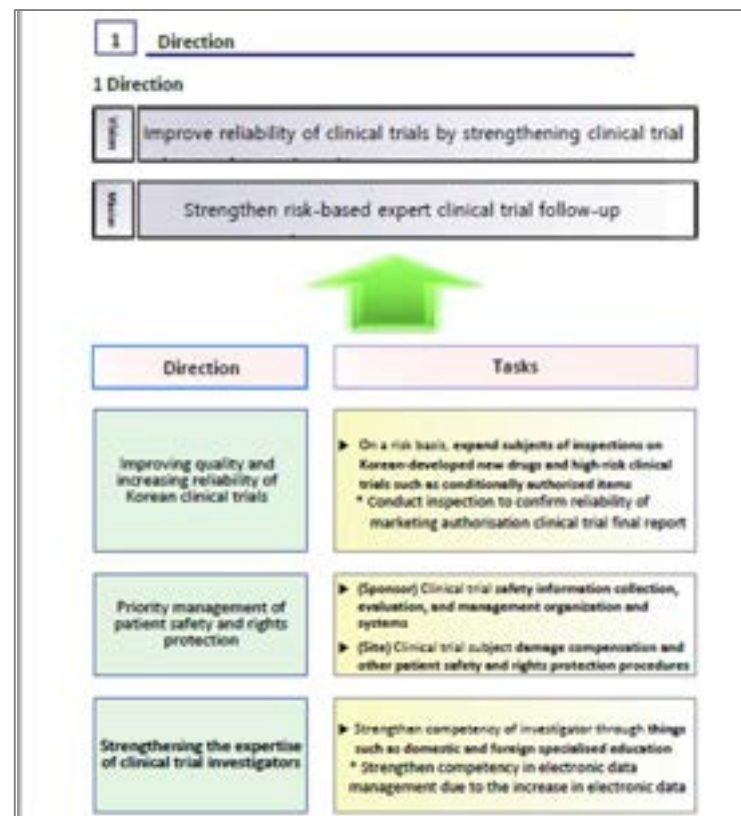
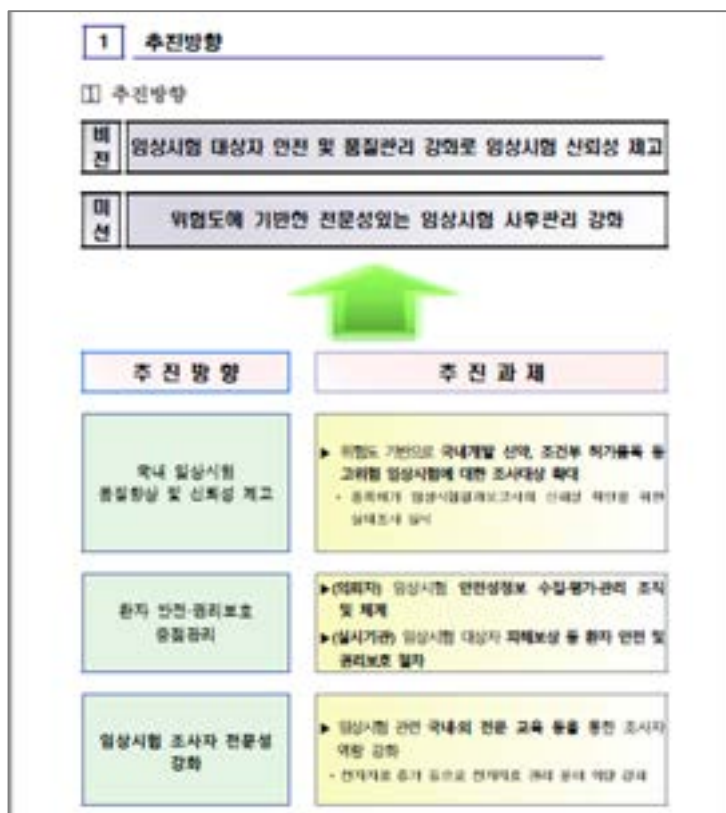
Comparison Tables

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- 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

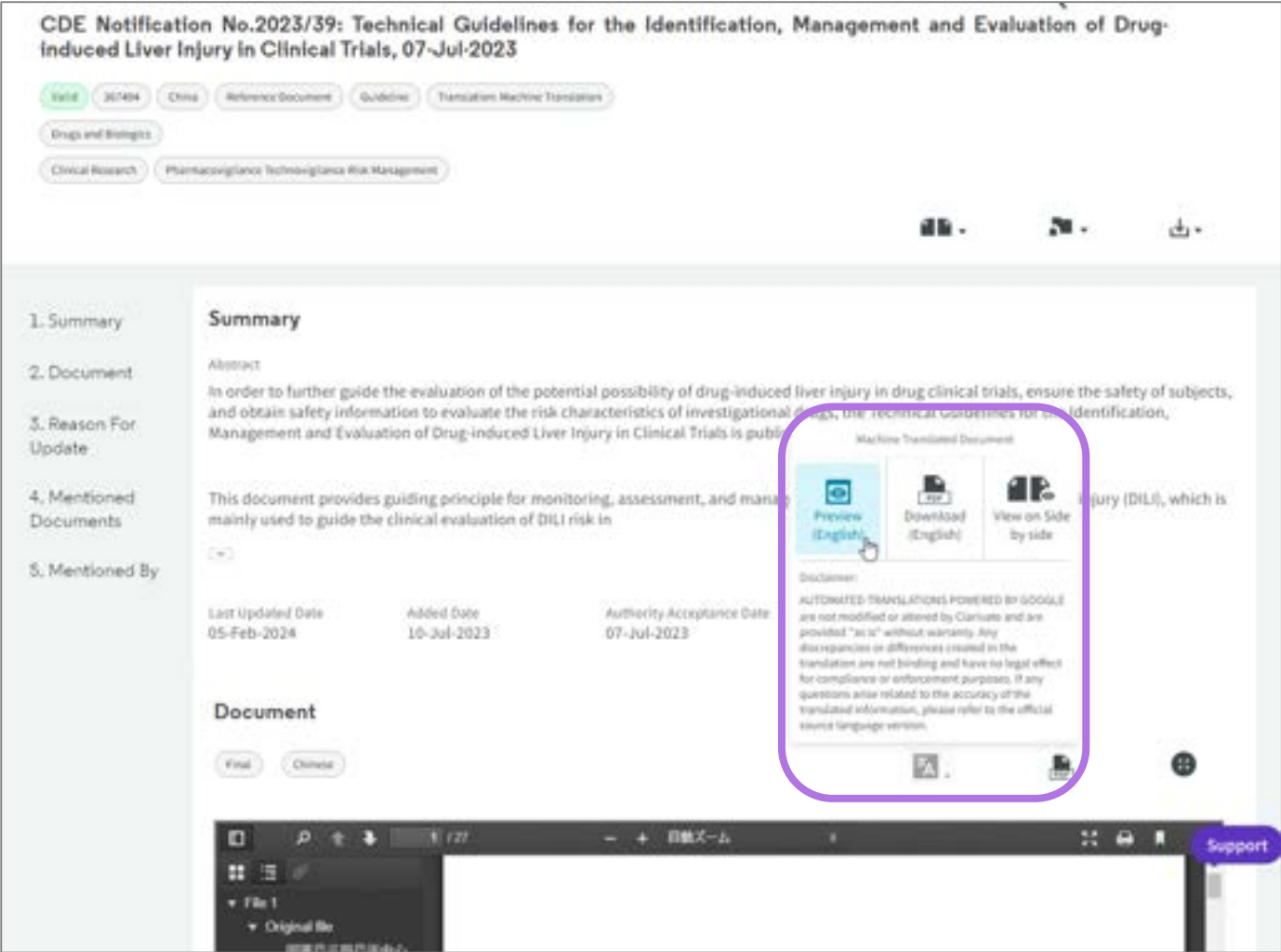
・規制文書の英語翻訳入手

- **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。

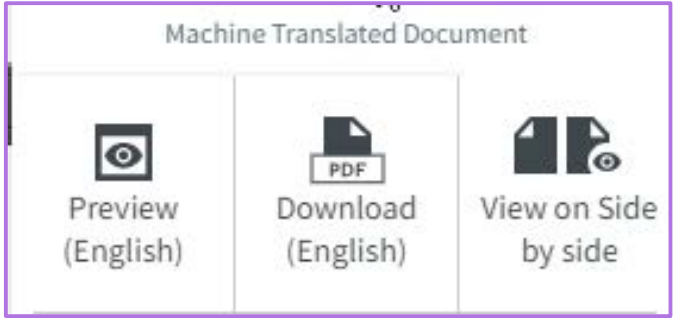


Cortellis Regulatory Intelligence – 2023年12月15日リリース

全収録国を対象とした規制文書の機械翻訳（英語）の追加



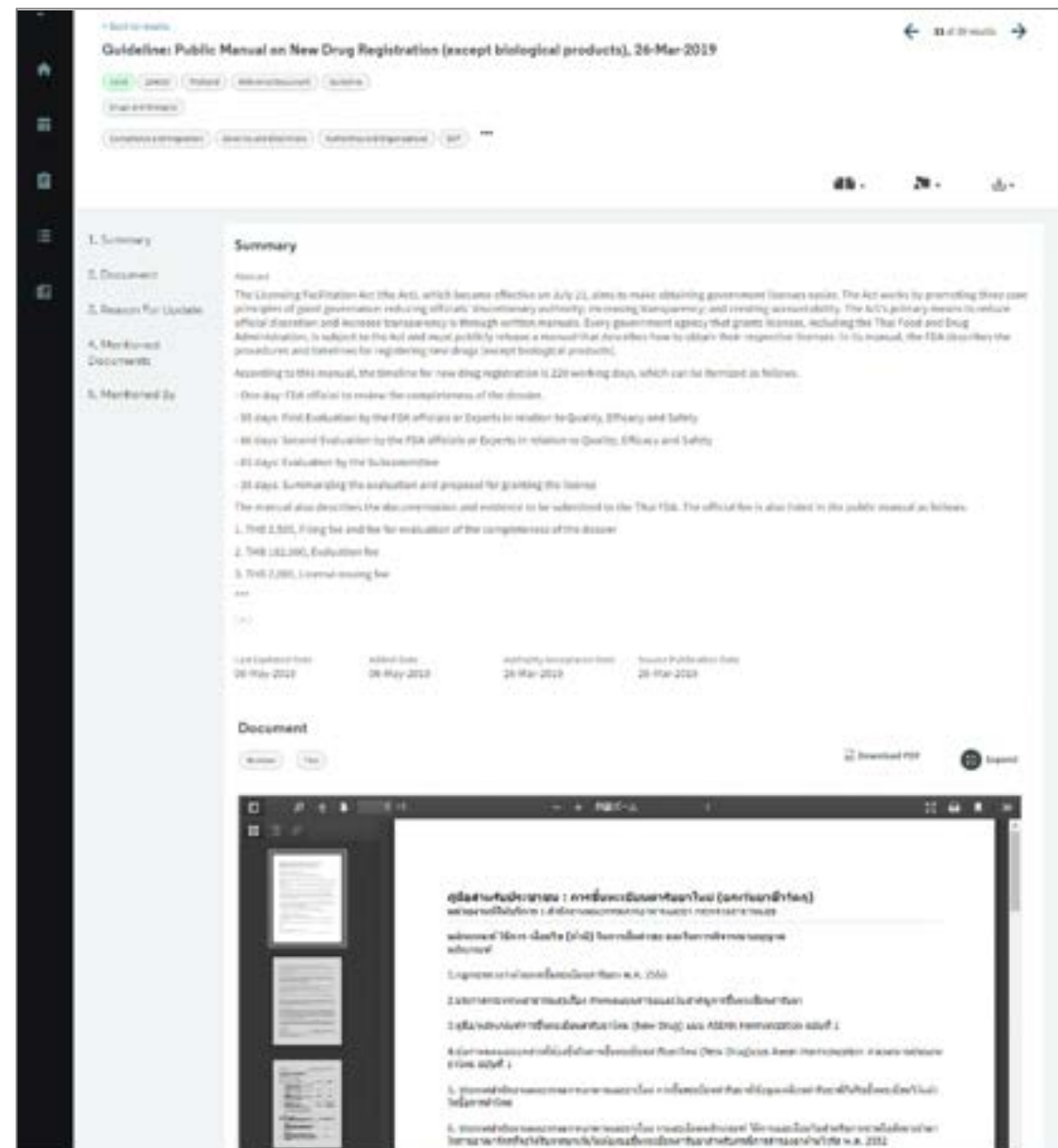
機械翻訳アイコンをクリックすると、翻訳済みの文書を表示またはダウンロードするためのメニューが表示されます。



- 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

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。
発行日や 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。



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



Reference Documents (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
- Drugs & Biologics: 8か国
 - Medical Devices & IVDs: 16カ国



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
 - ガイドライン一覧
 - FDA査察情報
 - 等



Comparison Tables

- 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

・ 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 °C/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

規制の比較表のアクセス方法はこちら↓でも確認できます
[CortellisクイックガイドNo.8](#)（Cortellisサポートサイトのリンク）

Comparison Tablesへのアクセス

The screenshot shows the 'Regulatory' section of the Clarivate interface. At the top, there are five tabs: 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The 'Comparison Tables' tab is highlighted with a blue box. Below the tabs, there are two main sections: 'Browse' and 'Search'. The 'Browse' section has a 'Filter by' dropdown menu set to 'Country / Region'. Below this, there are two columns of content. The left column is titled 'Drugs and Biologics' and contains 'Brexit Tracker' (with a sub-link 'European Union'), 'Citizen Petitions' (with a sub-link 'Petitions'), and 'Committee Meetings and Experts' (with a sub-link 'Advisory Committees'). The right column is titled 'Medical Devices & IVDs' and contains 'Committee Meetings and Experts' (with sub-links 'Advisory Committees', 'FDA Workshops', and 'France'), and 'Compliance and Inspections' (with sub-links 'Inspectors Table' and 'Warning Letters Overview'). A blue box with the text 'Comparison Tablesのタブをクリックしトピックの一覧を開く' (Click the Comparison Tables tab to open the list of topics) has an arrow pointing to the 'Comparison Tables' tab.

Regulatory

All Comparison Tables Intelligence Reports Regulatory Summaries Source Documents

Browse Search

Filter by Country / Region

Drugs and Biologics

Brexit Tracker

European Union

Citizen Petitions

Petitions

Committee Meetings and Experts

Advisory Committees

Medical Devices & IVDs

Committee Meetings and Experts

Advisory Committees

FDA Workshops

France

Compliance and Inspections

Inspectors Table

Warning Letters Overview

Expand all Collapse all

Comparison Tablesのタブをクリックしトピックの一覧を開く



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できるWeekly Alertメール
- 規制のモニタリングに活用できるレポート例のご紹介
- 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”

最新規制情報のモニター 速報eメールサービス

- Weekly Alert
 - 全てのユーザー様対象
 - 収録各国の最新規制、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
(Adcomm BulletinはUSモジュールにアクセスをお持ちのユーザー様に配信をしております)

China - Back to Top

Reference Documents (2)
Announcement; Guideline; Public Comment (1)

Guideline; Letter; Public Comment (1)

- China - CFDA Announcement: Soliciting Public Comment on 3 Annexes of Guideline - Chinese Good Supply Practice (GSP) Guidelines (Draft), 14-Oct-2016
In order to implement the updated Good Supply Practice (GSP) (IDRAC 230550), China Food and Drug Administration (CFDA) drafted three annexes:
Annex 1: Internal audit management (for quality control system)
Annex 2: Drug retail chain management
Annex 3: Drug retail pharmaceutical service standards
Comments: Deadline for comments: 18-Nov-2016
Full report (IDRAC 234132)
Document date: 14-Oct-2016
Document type: Announcement; Guideline; Public Comment
Regulatory version: Draft
Language: Chinese
Source; Publication Date: Obtained from CFDA website.
www.sda.gov.cn
18-OCT-2016

Back to China

- China - CFDA Letter: ShiYaoJianYaoHuaJianB of Guideline - Chinese Good Manufacturing Practice (GMP) Guidelines (Draft), 14-Oct-2016
This letter aims to solicit public comment on the Attachment of Drugs. This draft contains the applicable scope, general principles of manufacturing and quality control.
The feedback form is attached in Annex 2.
Comments: Deadline for comments: 12-Nov-2016
Full report (IDRAC 234144)
Document date: 14-Oct-2016
Document type: Guideline; Letter; Public Comment
Regulatory version: Draft
Language: Chinese

AdComm Bulletin
Read it first. Read it fast.

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

Today's Headline:
Unanimous Support Given to New UC Indication for Xeljanz

March 8, 2018
Meeting Begin Time: 8:05 a.m. | End Time: 3:36 p.m.

IN THIS ISSUE

Gastrointestinal Drugs Advisory Committee Meeting

[AdComm Profiles and Voting Histories](#) (IDRAC 175864)

Subjects: Supplemental new drug application (sNDA) 203214/18: Xeljanz (tofacitinib), submitted by Pfizer, Inc. for the proposed treatment of adult patients with moderately to severely active ulcerative colitis who have demonstrated an inadequate response, loss of response, or intolerance to corticosteroids, azathioprine, 6-mercaptopurine, or tumor necrosis factor inhibitor therapy.

Announced in the Federal Register
[January 19, 2018](#) (IDRAC 268179) (Volume 83, Number 13)

Decision/Voting

During today's meeting, the Gastrointestinal Drugs Advisory Committee (GIDAC) unanimously supported approval of [supplemental new drug application](#) (IDRAC 37905) (sNDA) 203214/18 for [Xeljanz](#) (IDRAC 266539) (tofacitinib) 5 mg and 10 mg tablets, submitted by Pfizer Inc for the treatment of adult patients with moderately to severely active ulcerative colitis (UC). The committee stated that this population is desperate for more treatment options.

FDA Questions to the Committee	Vote		Comments
	Yes	No	
Do you recommend inclusion in the product label of the 10 mg twice daily (BID) dosing regimen for extended induction therapy for a total of 16 weeks in patients who have not achieved "adequate therapeutic benefit" by week 8?	15	0	
Do you recommend inclusion in the product	15	0	

 Clarivate™

収録コンテンツの4つのカテゴリ

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



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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
	Title	Date	ICH Category	ICH Code	ICH Topic	ICH Step	Guidance Bulletin	Country	Local implementation	Date
1	ICH Draft Guideline: Routes of Administration Controlled Vocabulary (developed by the ICH M5 Expert Working Group), 10-May-2005 (IDRAC 51044)	10-May-2005								
2	ICH Draft Guideline: Units and Measurements Controlled Vocabulary (developed by the ICH M5 Expert Working Group), 10-May-2005 (IDRAC 51045)	10-May-2005								
3	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
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	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
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	European Union	CPMP/ICH/275/95 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 10953)	Jun-1995
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	Japan	Notification PAB/PCD No. 592: ICH Guideline (E1A, Step 4), the Extent of Population Exposure to Assess Clinical	24-May-1995

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



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	
	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
1	319082	319077	Draft Guidance for Industry: Premenopausal Women With Breast Cancer: Developing Drugs for Treatment, Oct-2020	07-Oct-2020	07-Dec-2020	322493	Public Comment (FDA-2020-D-1553): Society for Women's Health Research, 07-Dec-2020	331635
181	319082	319077	Draft Guidance for Industry: Premenopausal Women With Breast Cancer: Developing Drugs for Treatment, Oct-2020	07-Oct-2020	07-Dec-2020	322492	Public Comment (FDA-2020-D-1553): Tolmar, Inc., 30-Nov-2020	331635
182	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-0908): Bristol-Myers Squibb, 26-Oct-2020	332434
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	320319	Public Comment (FDA-2020-D-0908): Edison Oncology et al, 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	320325	Public Comment (FDA-2020-D-0908): Novartis Pharmaceuticals Corporation, 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	320321	Public Comment (FDA-2020-D-0908): Merck & Co. Inc., 07-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	320320	Public Comment (FDA-2020-D-0908): The University of Texas MD Anderson Cancer Center, 26-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	320590	Public Comment (FDA-2020-D-0908): Regeneron Pharmaceuticals, Inc., 26-Oct-2020	332434
262	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	332250
391								

Regulatory Intelligence Reportへのアクセス

The screenshot shows the 'Regulatory' section of a web application. At the top, there are five tabs: 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The 'Intelligence Reports' tab is highlighted with a blue box. Below the tabs, there are two main sections: 'Browse' and 'Search'. The 'Browse' section has a 'Filter by' dropdown menu set to 'Country / Region'. Below this, there are two columns of content. The left column is under 'Drugs and Biologics' and includes 'Brexit Tracker', 'European Union', 'Citizen Petitions', 'Petitions', 'Committee Meetings and Experts', and 'Advisory Committees'. The right column is under 'Medical Devices & IVDs' and includes 'Committee Meetings and Experts', 'Advisory Committees', 'FDA Workshops', 'France', 'Compliance and Inspections', 'Inspectors Table', and 'Warning Letters Overview'. A blue box with an arrow points to the 'Intelligence Reports' tab, containing the text: 'Intelligence Reportsのタブをクリックしてトピックの一覧を開く'. At the top right of the content area, there are icons for 'Expand all' and 'Collapse all'.

Regulatory

All Comparison Tables Intelligence Reports Regulatory Summaries Source Documents

Browse Search

Filter by Country / Region

Drugs and Biologics Medical Devices & IVDs

Brexit Tracker

European Union

► Citizen Petitions

► Petitions

► Committee Meetings and Experts

► Advisory Committees

► Committee Meetings and Experts

► Advisory Committees

► FDA Workshops

France

► Compliance and Inspections

► Inspectors Table

► Warning Letters Overview

Expand all Collapse all

Intelligence Reportsのタブをクリックして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

Document

None

English

Download Excel

Expand

1 / 1

自動ズーム

xlsx-report-136082.xlsx

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.

Name	Active Ingredient(s)	Application/ Submission Type	Application Number	Active Substance Status
MENS ROGANE	minoxidil	sNDA	21812/016	Known active substance
CADUET	amlodipine ; atorvastatin	sNDA	21540/047	Known active substance
GONAL-F RFF	folitropin alfa	sELA	21765/013	Known active substance
GONAL-F RFF	folitropin alfa	sELA	21765/014	Known active substance
GONAL-F RFF	folitropin alfa	sELA	21765/044	Known active substance
PROGRAF	tacrolimus	sNDA	210115/004	Known active substance
ASTAGRAF XL	tacrolimus	sNDA	204096/009	Known active substance
GONAL-F	folitropin alfa	sNDA	20378/045	Known active substance
GONAL-F	folitropin alfa	sNDA	20378/067	Known active substance
GONAL-F	folitropin alfa	sNDA	20378/075	Known active substance
JALYN	dutasteride ; tamsulosin hydrochloride	sNDA	22460/011	Known active substance
MARGENZA	margetuximab-onlv	sNDA	761150	New active substance
OPDIVO	nivolumab	sELA	125554/095	New active substance
FENTORA	fentanyl citrate	sNDA	21947/030	Known active substance
SUBSYS	fentanyl	sNDA	202708/021	Known active substance
LAZANDA	fentanyl	sNDA	22569/029	Known active substance

どちらの方法でも
同一のExcelファイルを
ダウンロードできます



4. 欲しい文書が探せなくて困っていませんか？ 強化された検索機能と各国規制エキスパートによるサポート

- 検索機能の操作方法と、アラート設定による新規文書、規制変更のモニタリング
- 現地語での規制文書検索に対応



検索方法1

ホーム画面でのQuick Search

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

The screenshot shows the 'Regulatory' search interface. At the top, there are tabs for 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. A blue callout points to the 'All' tab, stating: 'ここでは“All”のタブでの検索機能 (Quick Search)を使用します'. To the right, there are checkboxes for 'Drugs & Biologics' (checked) and 'Medical Devices & IVDs'. Below the tabs is the 'Quick Search' section, which includes a search input field containing the text '"risk management plan"', a blue 'Search' button, and a grey 'Advanced search' button. A blue callout points to the 'Search' button, stating: 'キーワードを入力し “Search”をクリック'. Below the search input is a 'Filter' section with buttons for 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date', 'Translation Status', and 'All other filters'. A blue callout points to this filter section, stating: '予めフィルターで複数の検索条件を指定できます'. On the far left, there is a dark vertical sidebar with several icons, including a home icon and a list icon.

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 国の指定

Document title, topic, country, reference

Search Advanced search

Filter

Country/Region Topic Document Type Document Category Date All other filters Reset filters

Country/Region

USA (108853) European Union (58105) Canada (3810) France (5630) Japan (4401) South Korea (3068) Brazil (1146) China (2945)

United Kingdom (2896) International (2889) Switzerland (2131) Germany (2129) Italy (2108) Taiwan (1946) Denmark (1856) Portugal (1753)

Turkey (1635) Spain (1617) India (1596) Sweden (1412) Australia (1276) Argentina (1170) Colombia (1169)

Cancel Apply

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 規制トピックの指定

Document title, topic, country, reference

Search Advanced search

Filter

Country/Region Topic Document Type Document Category Date All other filters Reset filters

Clinical Research (2993) Generics and Biosimilars (2857) Authorities and Organizations (1376) Dossier Format and Submission (740)

Manufacturing and Control (570) Packaging and Labelling (435) Legislative Framework (423) Pharmacovigilance (410) Risk Management (410)

Product Assessment (316) Compliance and Inspection (245) Distribution (234) Prescription Requirements (234)

Cancel Apply

Topic: どの分野に関わる規制か トピックを選択

Search 文書の種類を指定

Document title, topic, country, reference

Search Advanced search

Filter

Country/Region Topic Document Type Document Category Date All other filters Reset filters

510(k) (27901) Supplemental Approval - NDA (11746) Federal Register Announcement (10508) Meeting (8529) Warning Letter (5467) Guideline (5821)

Inspection Report (5558) Public Comment (5045) Press Release (3648) Original Approval - NDA (2193) 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

Document Type: Guideline

Search

Document title, topic, country, reference

Filter

Country/Region Topic Document Type Document Category Date All other filters Reset filters

1 Regulatory Version

Final (120) Draft (311) Revision (83) None (15) Implementation (15)

Amendment (13) Withdrawn (1)

Languages

Search

Document title, topic, country, reference

Filter

Country/Region Topic Document Type Document Category Date All other filters Reset filters

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

Reg. Entry - All Results
34 results
Switch to Comparison Tables

標準の検索結果

Refine Search

Document title, topic, country, reference

Search

Filter

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

Side by Side Viewer

Showing 1-10 of 34 results

Customize Columns

Sorted by Relevance

Summary	Title	Abstract	Reason for Update
Jul-2009  US	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	Now on 11 Jun 2019. This document replaces the Draft Guidance for Industry: ANDAs - Impurities in Drug Substances
Aug-2004  US	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 (USDA, 40562) has been published in September 2003. This guidance is intended to assist	Formatting Change on 07-Jan-2019. This update contains a change to
Dec-2004  US	ICH - Guidance for Industry: M4 - The Common Technical Document (CTD) - Efficacy: Questions and Answers (Revision 1) (Final), Dec-2004	Current version. A previous ICH guidance has been published in May 2004 (ICHAC, Number 44274). This is one in a series of	N/A
Dec-2004  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 (ICHAC, Number 44274). This is one in a series of	Formatting Change; Final guidelines are not available

①=Valid, 最新版文書

Reg. Entry - All Results
83 results
Switch to Comparison Tables

旧バージョン文書を含む検索結果

Refine Search

Document title, topic, country, reference

Search

Filter

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

Side by Side Viewer

Showing 1-10 of 83 results

Customize Columns

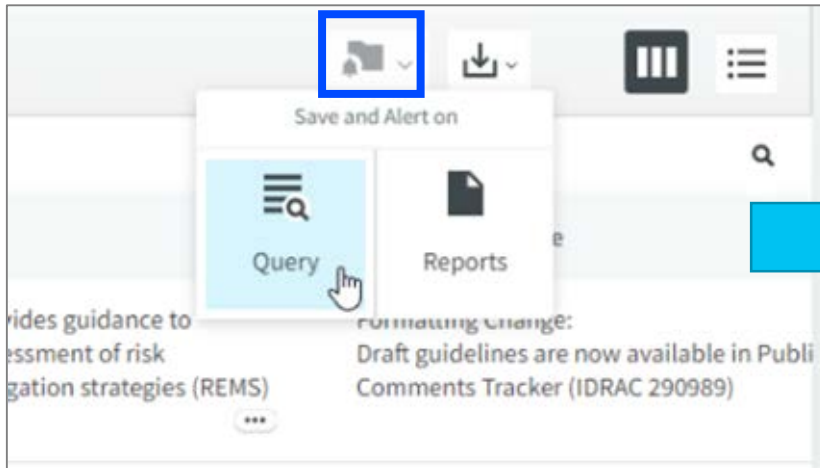
Sorted by Relevance

Summary	Title	Abstract	Reason for Update	Country/Region
Jul-2009  US	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	Now on 11 Jun 2019. This document replaces the Draft Guidance for Industry: ANDAs - Impurities in Drug Substances	USA
Jun-2008  US	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 06-May-2021: This document is outdated by a new version (IDRAC 113260) "Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Human Pharmaceutical Product Applications and Related"	USA
Apr-2006  US	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 12978) "Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Human Pharmaceutical Product Applications and Related"	USA
Aug-2005  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 (IDRAC 113260) "Guidance for Industry: ANDAs - Impurities in Drug Substances"	USA

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

⓪=Outdated, 旧バージョン文書

検索条件へのアラートを設定し 新たな規制の出現をモニタリング



検索結果右上のSave and Alert on
Query/Reportsをクリック

検索条件に合致する新規文書の収録や、
既存の文書の変更などを追跡するには
アラートを設定します

Save and Alert on

- Query:
検索条件に合致する文書の出現や
検索条件から外れる文書の追跡
- Reports:
各文書の更新情報の追跡

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)



検索方法2

Source Documents search

規制当局の文書の詳細検索

Source Documents(現地規制文書)検索の強化

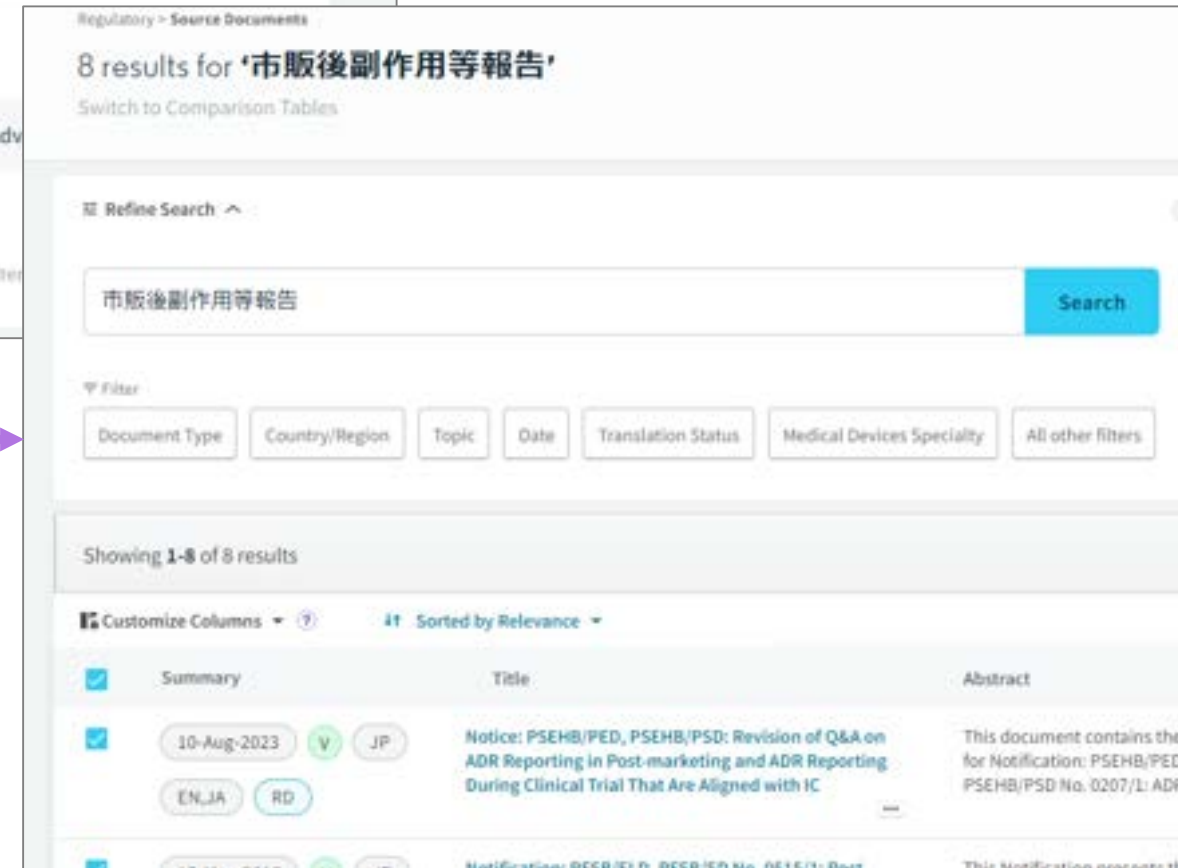
現地語を含む全文検索に対応



“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

- “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。





サポートのご案内

規制調査のサポート エキスパートの知見を活用

- 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対応

Regulatory Consultants

Clarivate Analytics professional regulatory intelligence specialists work with an international network of consultants, each with an in-depth local expertise.

As a result, each Cortellis Regulatory Intelligence™ country module contains detailed and continuously updated Regulatory Summaries written by experts from the region.

Select a country ▼



ユーザーサポートまとめ

日本語サポートサイト

<https://clarivate.com/cortellis/ja/learning/cortellis-training-home-1564/>

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/cortellis/ja/training-webinars/>

ユーザー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。



顧客別・部署別講習会の提供

画一的な利用説明会ではなく、事前のヒアリングを経たユーザーニーズに沿ったデータベース講習会を開催しています。

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。



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。

カスタマーケア

☎ 0800-170-5577(フリーダイヤル)
(土日祝日を除く) 9:30~17:30
✉ ts.support.jp@clarivate.com

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。



Appendix 1

Cortellis Regulatory Intelligence

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



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

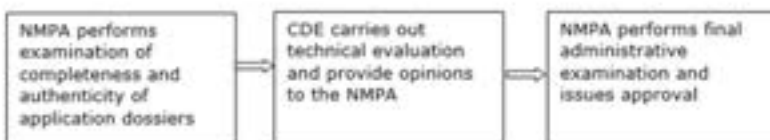
Approval Procedure and Timeline

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:



Country/Region	Climatic Zone	Requirements for Site Specific Stability Data	Long-Term (real time) Testing Conditions	Long-Term (real time) Testing Conditions Notes
Algeria	8	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.	25deg. C <math>\pm</math>10mm, 28deg. C/60% RH <math>\pm</math>10mm, 5% RH	For refrigerated storage: 5deg. C <math>\pm</math>10mm, 3deg. C
Argentina	8	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.	25deg. C <math>\pm</math>10mm, 28deg. C/60% RH <math>\pm</math>10mm, 5% RH	The Stability study should be carried out on three pilot batches, according to the guidelines described in the Pharmacopoeia Argentina V/Ed. <math>\pm</math>10deg. C, internationally recognized pharmacopoeias and/or ICH Q1 guidelines, 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		301502	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](#)

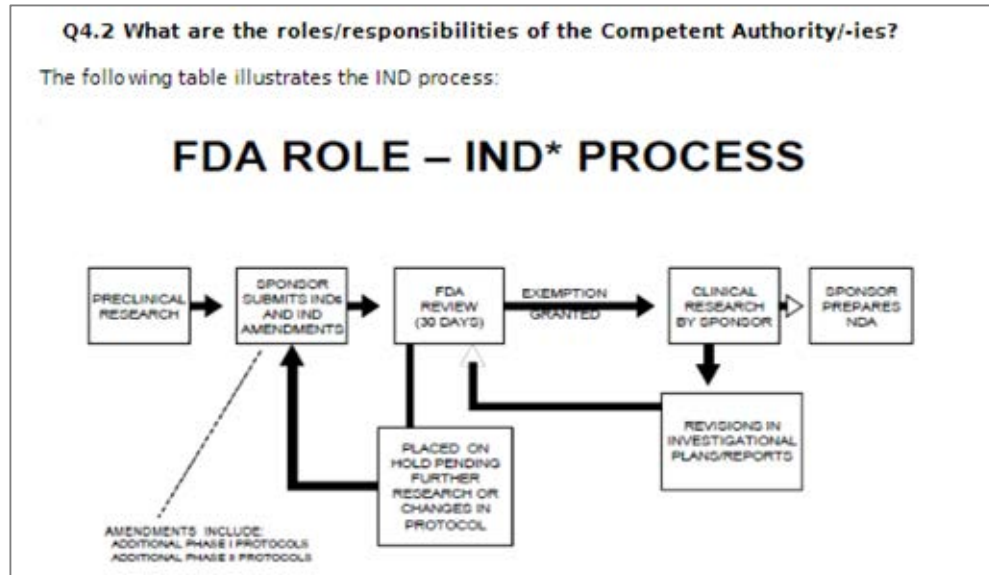
DEPARTMENT OF HEALTH AND HUMAN SERVICES BIOPRODUCTS DIVISION	
DISTRICT OFFICE AND PHONE NUMBER 8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax: (913) 495-5115	DATE OF REPORT 2/21/2018-2/6/2018* REPORT NUMBER 3007934624
NAME AND TITLE OF ESTABLISHMENT, INCLUDING REPORT NUMBER David E. Simchen, Medical Director WARNING:	
ESTABLISHMENT NAME The Fertility Partnership LLC CITY, STATE, ZIP+4 CODE Saint Peters, MO 63376-1457	STREET ADDRESS 5401 Veterans Memorial Hwy Ste 201 TYPE OF PRODUCT MANUFACTURED 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



Required data in product categories

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

Data to be submitted	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	Carcinogenicity	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 JEMPERLI's 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.

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

Market Access Overview: China
National Market Access Hurdles

Source: NMPA, National Medical Products Administration; CDE, Center for Drug Evaluation; NPD, National Institute of Food and Drug Control; National Healthcare Security Administration (NHSA); NHSA, National Reimbursement Drug List

	Clinical Trial	Market Authorization	Price Setting	Reimbursement Determination	Reimbursement Review
	Average approval: 3 months	Average approval for NDA: 12-15 months; ND 100 days for registered generics	No specific timeline (usually shortly after obtaining NDA)	Usually, one year after market entry	First approval, variable, usually delayed
	NMPA (CDE) & NPD	NMPA	Manufacturers	NHSA	NHSA & State Council
Pre-submission	- 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	- Searches drugs for approval - 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 formulary policies
Decision Criteria	- Completeness of application - Applicability for local population - Prevalence for: - Expected health benefit - Financial impact - Population needs - Local manufacturers	- Completeness of clinical trial data - Clinical efficacy, safety, and quality - Data validity and applicability for the Chinese population	- Free-market pricing - Prices must align closely with general pricing principles based on the principles of fairness, rationality, timeliness, 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 have aligned China's approval process more closely to global standards	Free-market mechanisms will enable drug prices accessible to consumers; reimbursement and procurement policies will apply downward pressure on prices	Strikes to achieve balance between low prices and low return to industry; to encourage further innovation	NRDL is revised 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

Regulatory Intelligence Report
Deep dive analysis from Cortellis

Market Access Overview: China
Cost-Containment Strategies

Source: NMPA, National Medical Products Administration; CDE, Center for Drug Evaluation; NPD, National Institute of Food and Drug Control; National Healthcare Security Administration (NHSA); NHSA, National Reimbursement Drug List

Increasing Degree of Impact	Strategy	Description
High	Volume Based Purchasing (VBP)	- Provincial level bidding involves submission of bids by manufacturers to Joint Procurement Office (JPO) - Lowest bidders are guaranteed purchase amount from provinces
Medium-High	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 (10-60% reimbursement)
Medium	Centralized Drug Procurement	- Centralized procurement uses a double-envelope bidding system under which manufacturers compete 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
Medium-Low	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
Low-Medium	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
Low	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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Appendix 2

規制分析コンテンツトピック紹介

収録コンテンツの4つのカテゴリ

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



Reference Documents (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
- Drugs & Biologics: 8か国
 - Medical Devices & IVDs: 16か国



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
 - ガイドライン一覧
 - FDA査察情報
 - 等



Comparison Tables

- 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

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） トピックス一覧– 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

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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