

Cortellis CMC Intelligence User Guide

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Cortellis CMC Intelligenceとは

Cortellis CMC Intelligence は、
低分子医薬品およびバイオリジクス製品に関する世界各国のCMC要件を網羅するデータベースです。
大きく移り変わるグローバル薬事規制環境下において、
最新のCMC要件を提供し、効率的な薬事申請をサポートします。

各国の規制当局の公式文書や、現地規制に精通したスペシャリストの知見によって収集された情報を
活用し、各国のCMC規制要件に関する効率的な情報収集を可能にします。

CMC Intelligence ログインページ : <https://www.cortellis.com/cmc>

Home page | 概要

- データベースを使用するには、ホーム画面で調査対象の製品カテゴリ(Small MoleculesおよびBiologics両モジュールにアクセス権をお持ちのユーザー様のみ) および調査対象の国・地域・組織を選択します
- 製品カテゴリや国などの選択方法は次頁以降で解説します

Home

Summary

Detailed

Report

Updates

Alerts

Cortellis

Small Molecules

Biologics

Countries / Territories (23)

Regions

Organizations

Member States

Climatic Zones

Select Countries / Territories

Countries / Territories Selected (23)

Afghanistan

Australia

Bangladesh

Bangladesh Procurement Agency

Cambodia

China

China Procurement Agency

Hong Kong

India

India Procurement Agency

Indonesia

Japan

Malaysia

Myanmar

Nepal

New Zealand

Pakistan

Philippines

Clear all

Go to: Summary Detailed Report Updates

Summary

Detailed

Report

Updates

ホーム画面（本頁で示している画面）に戻る

Small MoleculesとBiologicsのモジュール切替ボタン（該当ユーザー様のみ）

選択中の国・地域・組織表示エリア

画面左のパネル内のアイコンをクリックして、データベース内の異なるコンテンツ/機能を表示させます。このパネルは常に画面の左側に表示されています。

Cortellis CMC Intelligenceのコンテンツカテゴリの簡易説明

サポートメニューを表示します（英語）

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Legal center

Privacy notice

Cookie policy

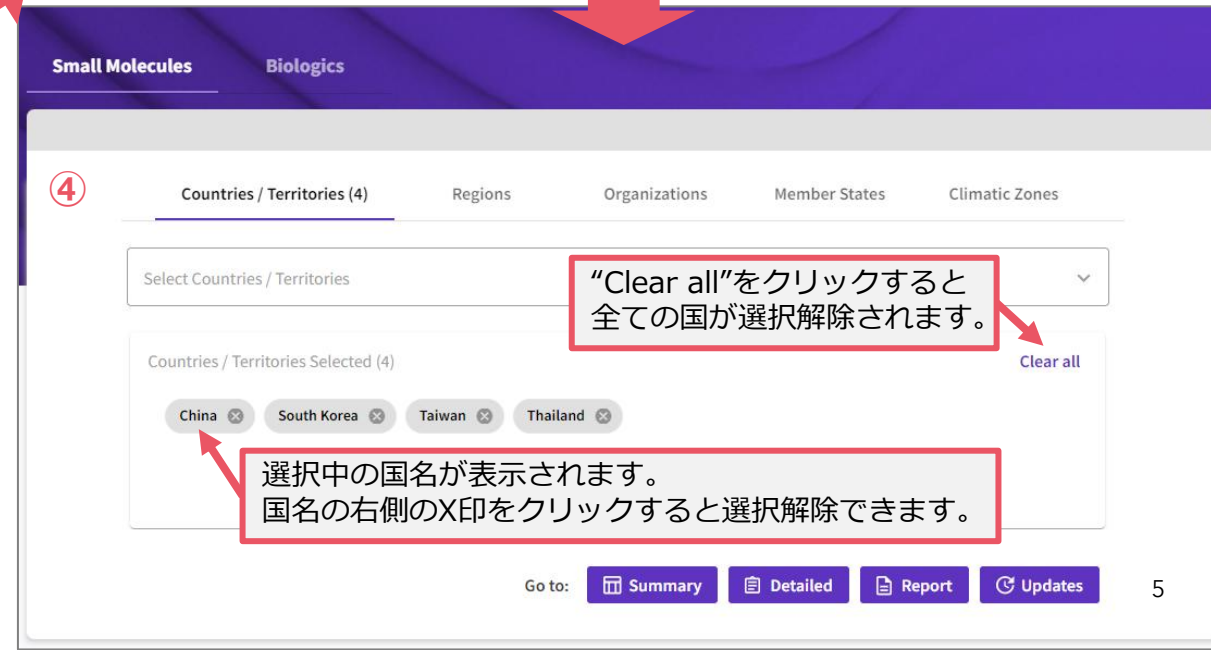
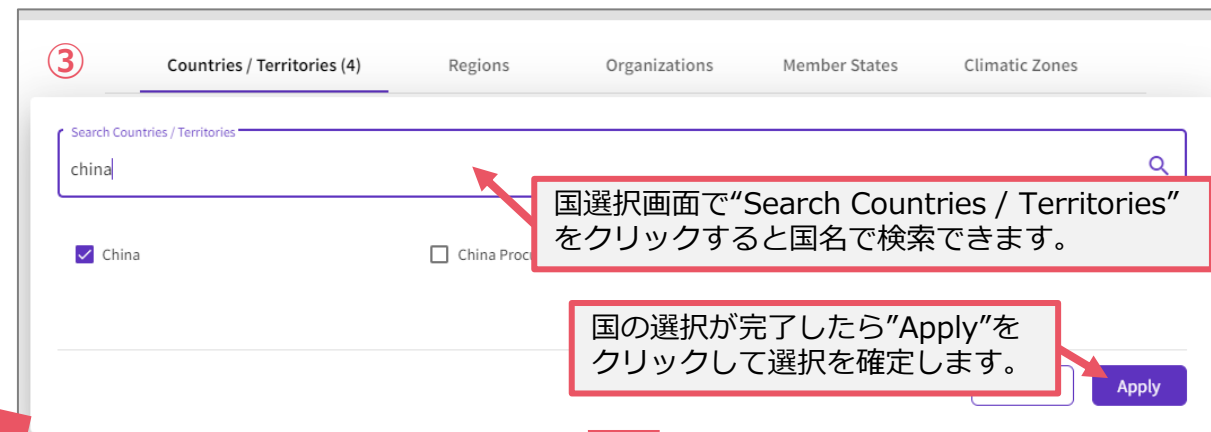
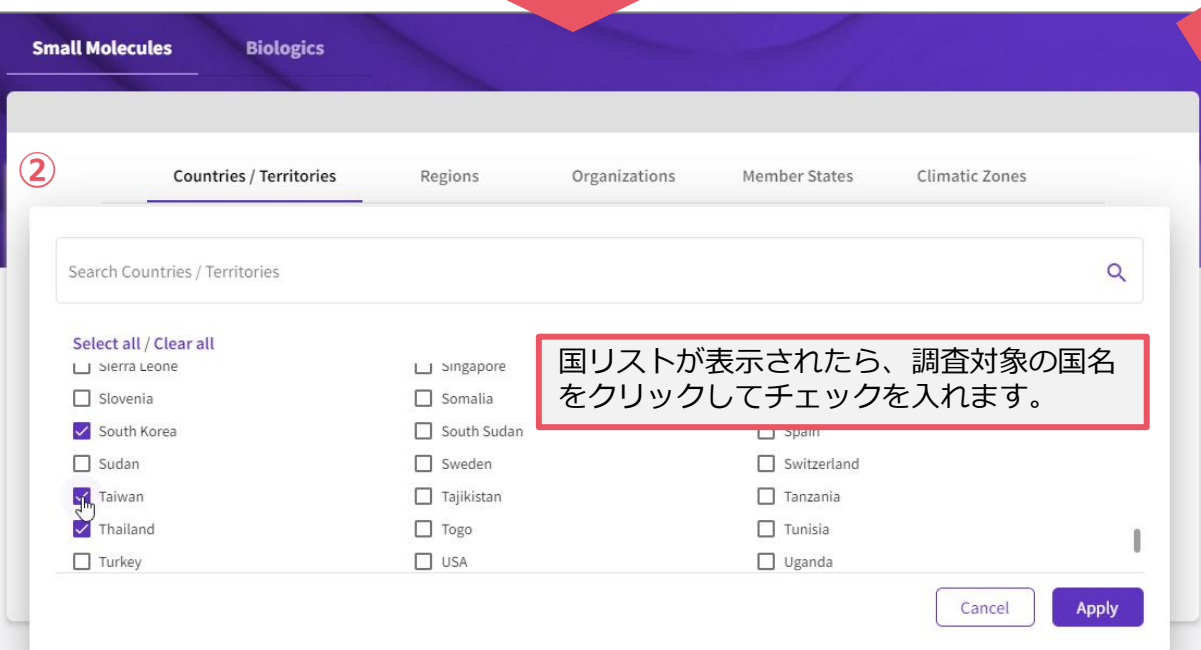
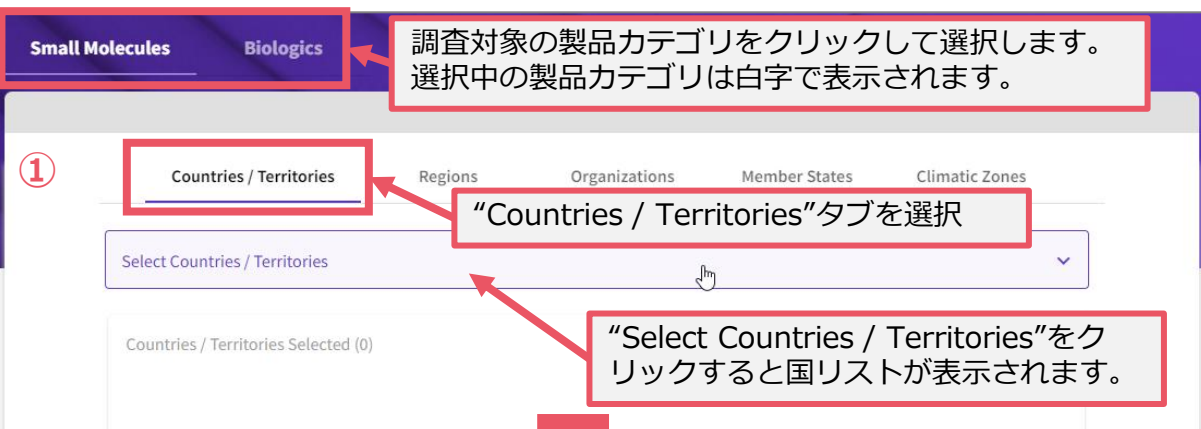
Manage cookie preferences

6 Support

Home page | Countries/Territories - 国の選択

CMC要件のコンテンツを閲覧するには、関心のある国や地域を選択する必要があります。

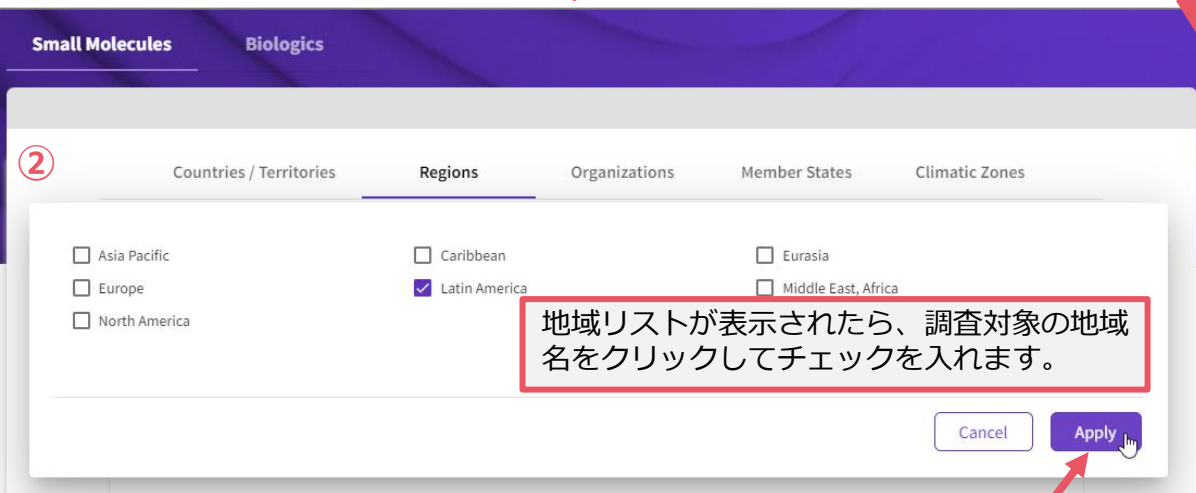
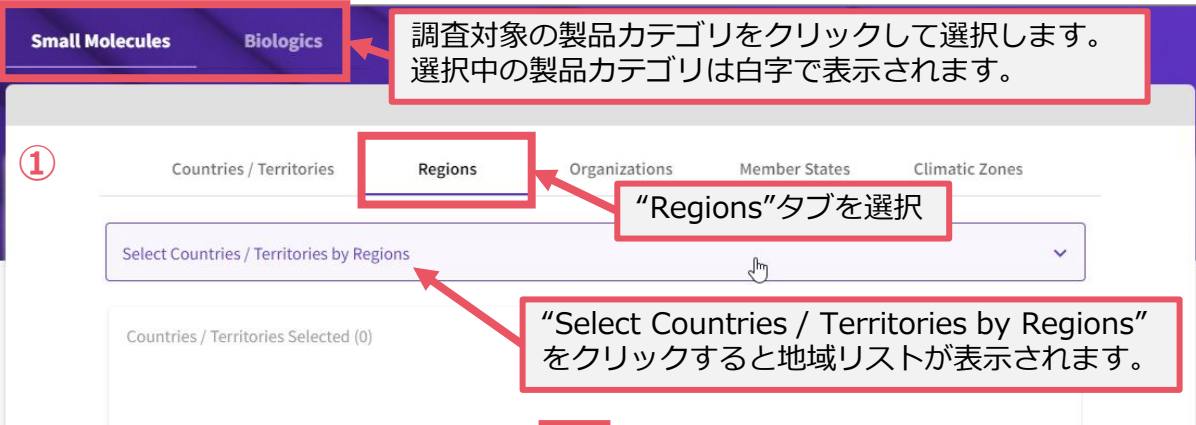
- まずSmall MoleculesまたはBiologicsのどちらかをクリックして製品カテゴリを選択します（該当ユーザ様のみ）
- 次に“Countries/Territories”タブ内の“Select Countries / Territories”をクリックして、国名一覧から調査対象国を選択します
 - 目的の国がすぐに見つからない場合は“Search”検索も可能です



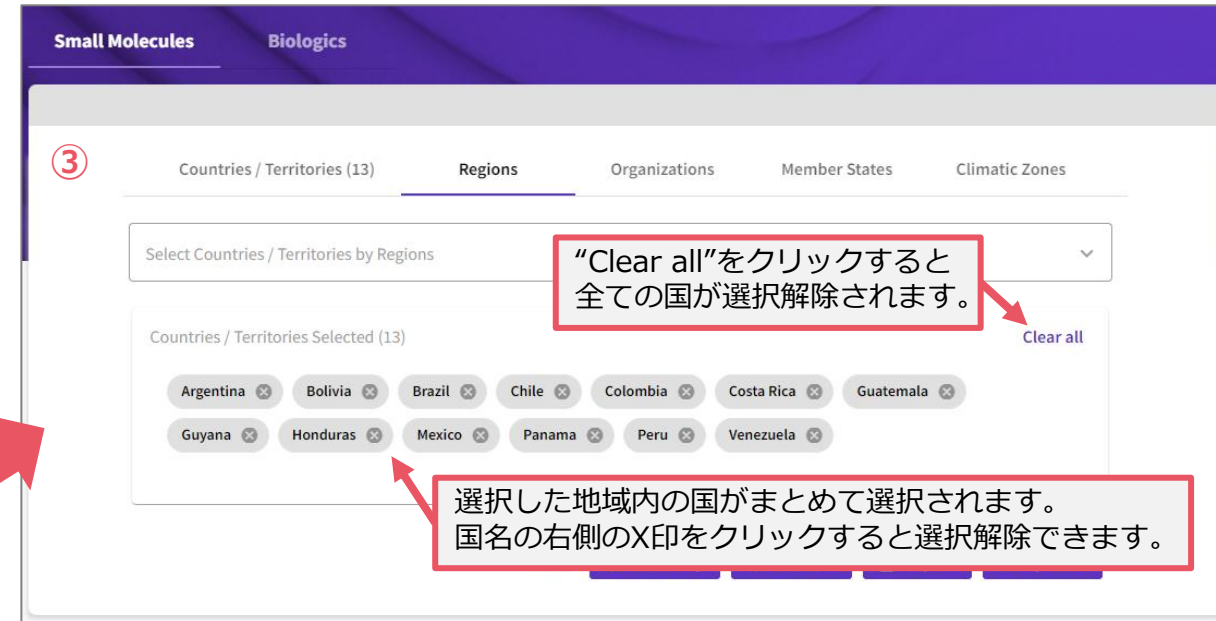
Home page | Regions - 地域を選択

CMC要件のコンテンツを閲覧するには、関心のある国や地域を選択する必要があります。

- まずSmall MoleculesまたはBiologicsのどちらかをクリックして製品カテゴリを選択します（該当ユーザ様のみ）
- “Regions”タブを使用すると、特定の地域の国をまとめて選択できます。



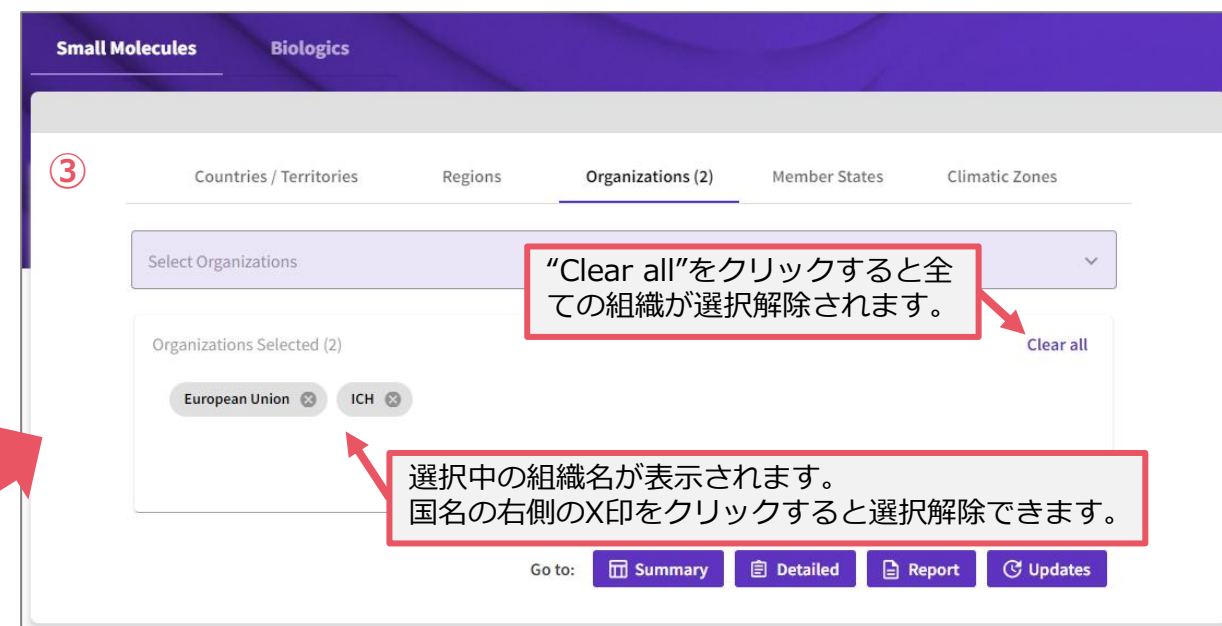
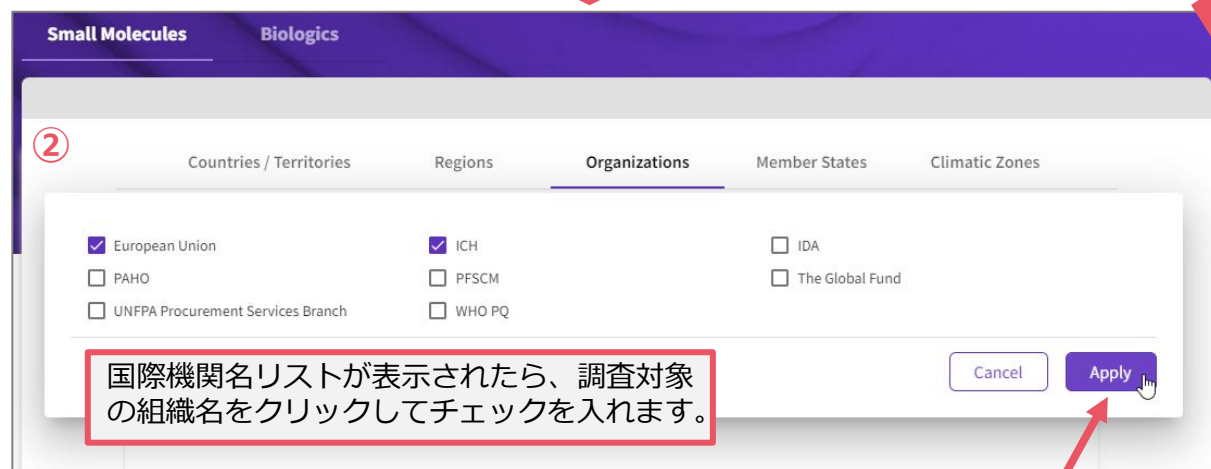
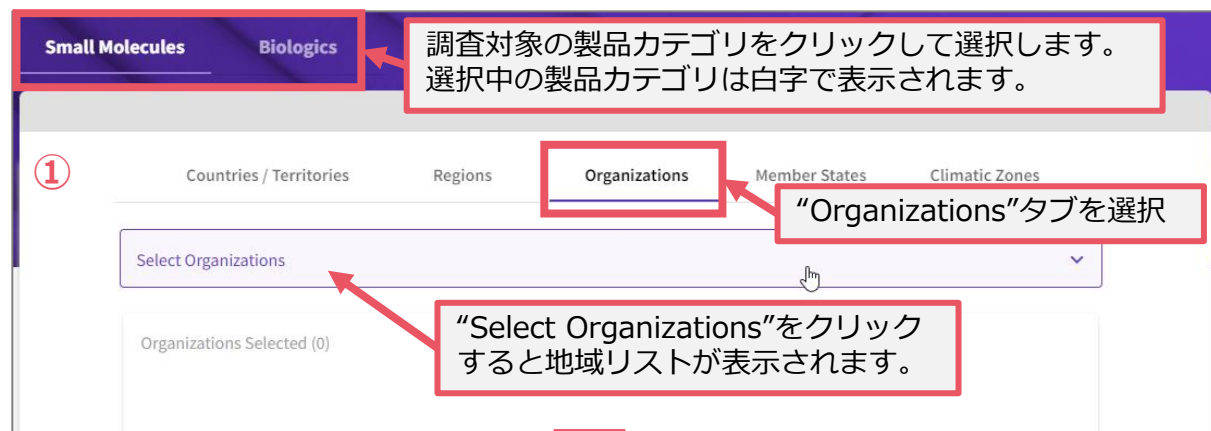
地域の選択が完了したら“Apply”をクリックして選択を確定します。



Home page | Organizations - 様々な組織の選択

CMC要件のコンテンツを閲覧するには、関心のある国や地域を選択する必要があります。

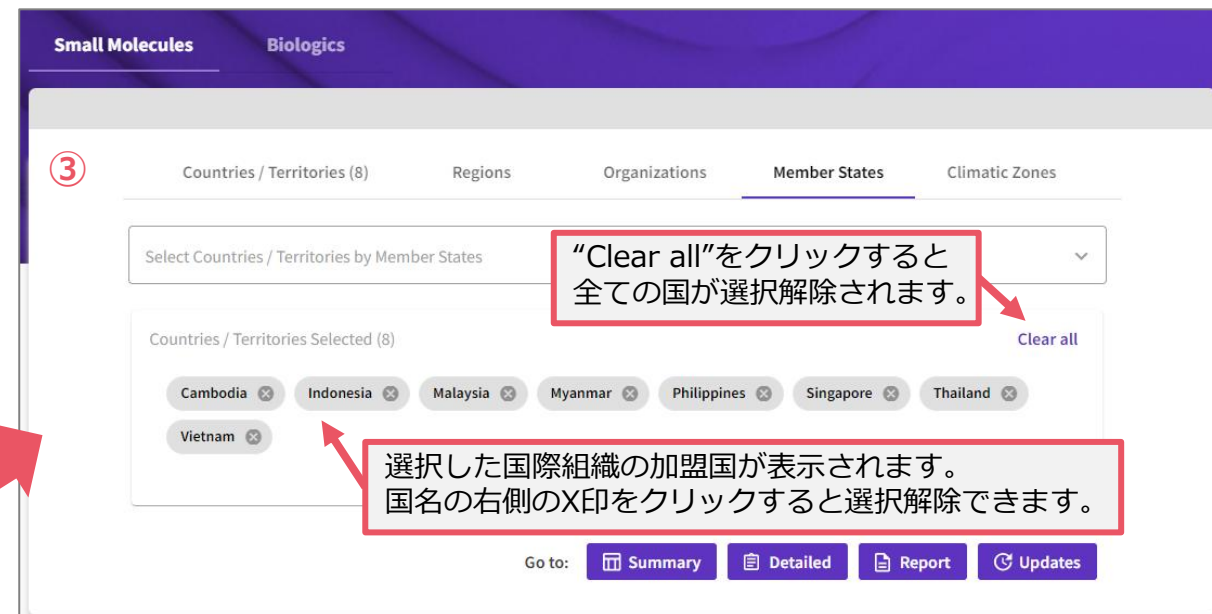
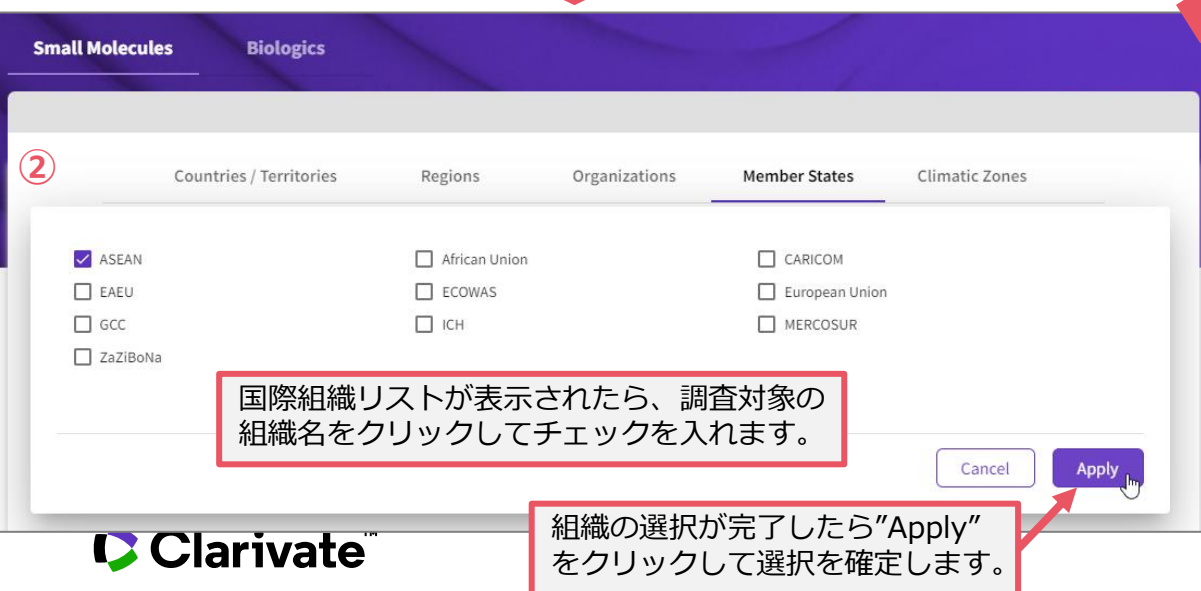
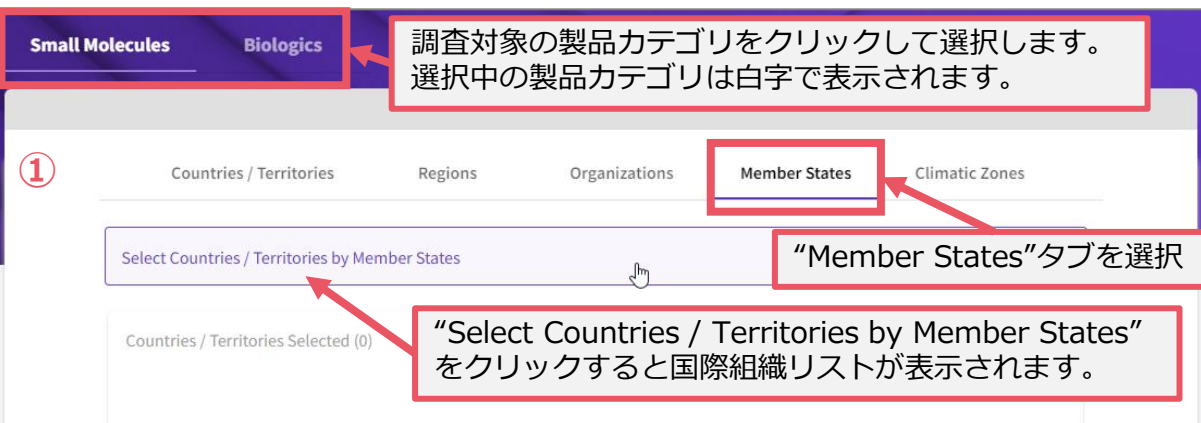
- まずSmall MoleculesまたはBiologicsのどちらかをクリックして製品カテゴリを選択します（該当ユーザ様のみ）
- “Organizations”タブを使用すると、規制情報の入手が可能な国際機関名を表示します。



Home page | Member States - 国際組織加盟国の選択

CMC要件のコンテンツを閲覧するには、関心のある国や地域を選択する必要があります。

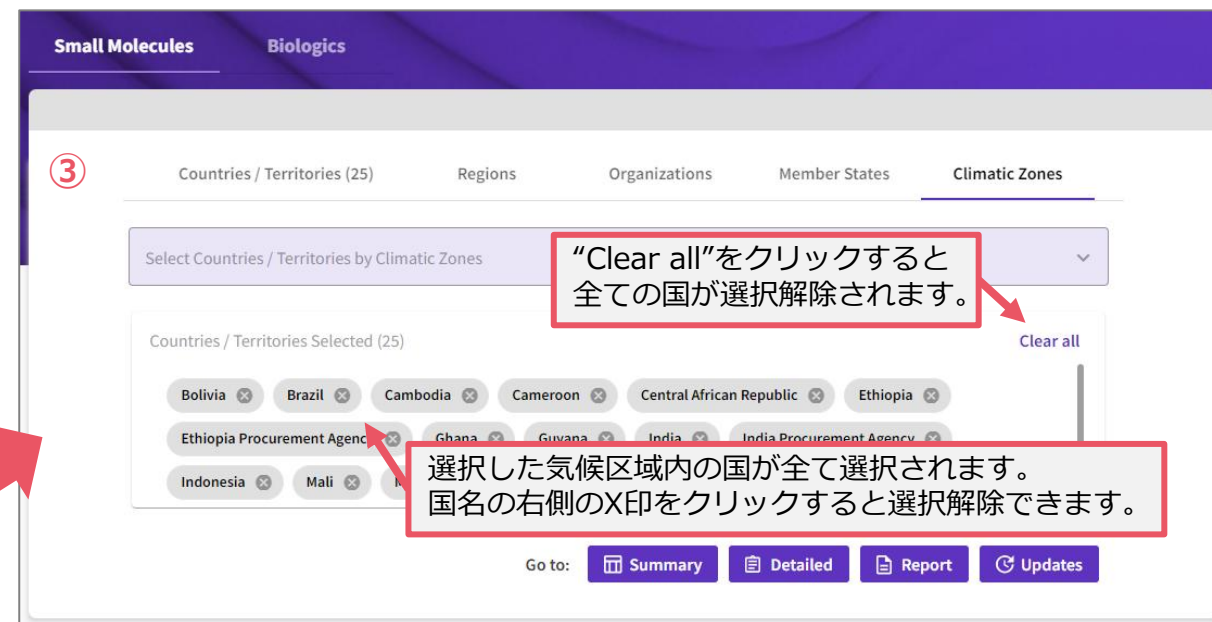
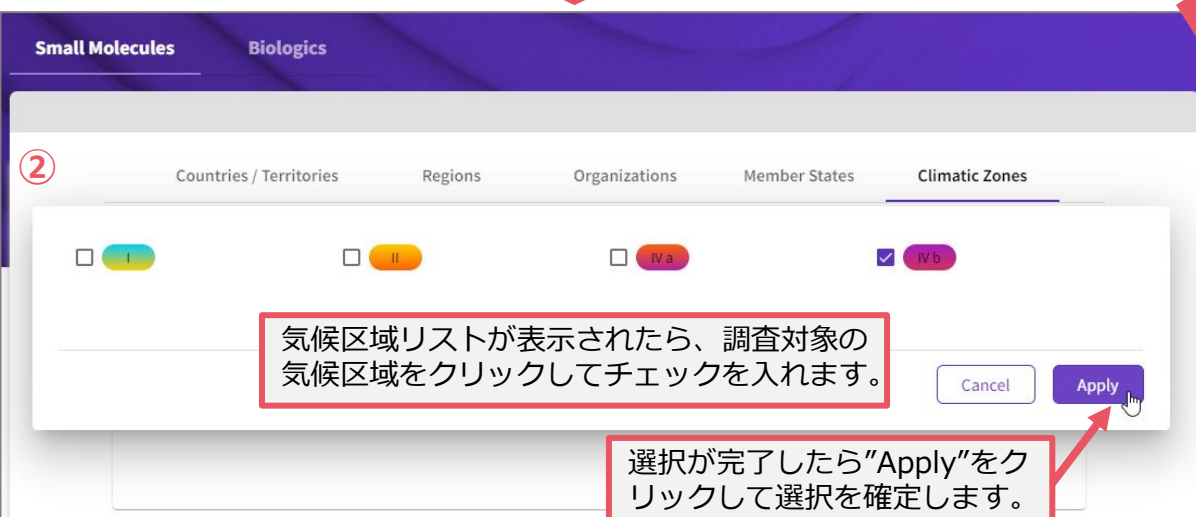
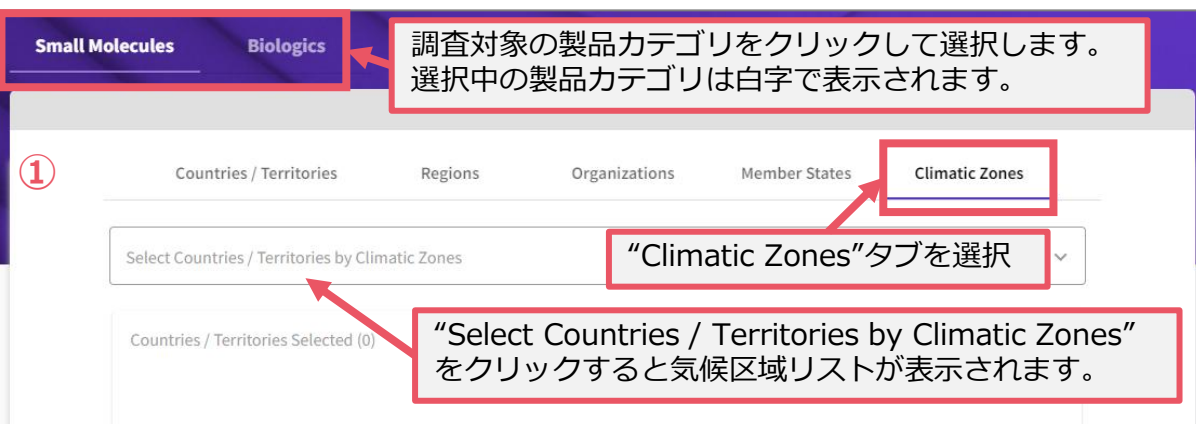
- まずSmall MoleculesまたはBiologicsのどちらかをクリックして製品カテゴリを選択します（該当ユーザ様のみ）
- “Member States”タブを使用すると、特定の国際組織の加盟国をまとめて選択できます。



Home page | Climatic Zones - 気候区域の選択

CMC要件のコンテンツを閲覧するには、関心のある国や地域を選択する必要があります。

- まずSmall MoleculesまたはBiologicsのどちらかをクリックして製品カテゴリを選択します（該当ユーザ様のみ）
- “Climatic Zones”タブを使用すると、特定の機構区域内の国をまとめて選択できます。



Home page | コンテンツへのアクセス

- 調査対象の国・地域・組織を選択すると、Cortellis CMC Intelligenceの各コンテンツにアクセスできるようになります

The screenshot shows the Cortellis CMC Intelligence Small Molecules homepage. A vertical sidebar on the left contains icons for Home, Summary, Detailed, Report, Updates, Alerts, and Cortellis. The main content area has tabs for Small Molecules and Biologics. Under Small Molecules, there are sub-tabs for Countries / Territories (4), Regions, Organizations, Member States, and Climatic Zones. A dropdown menu for 'Select Countries / Territories' is open, showing a list of selected countries: China, South Korea, Taiwan, and Thailand. Below this, there are buttons for 'Go to: Summary', 'Detailed', 'Report', and 'Updates'. At the bottom, there are four cards for Summary, Detailed, Report, and Updates, each with a brief description of the content.

Cortellis CMC Intelligence | Small Molecules

Small Molecules Biologics

Countries / Territories (4) Regions Organizations Member States Climatic Zones

Select Countries / Territories

Countries / Territories Selected (4) Clear all

China South Korea Taiwan Thailand

Go to: Summary Detailed Report Updates

Summary
Compare and contrast core requirements for your selections to identify differences and similarities

Detailed
Explore and search through, both official regulatory requirements and local practices organized into eCTD

Report
View a visualization of regulatory submission pathways, read key facts, procedures and requirements

Updates
See the latest updates to the content for your selected country or organization to quickly identify and

画面左のアイコンをクリックして、データベース内の異なるコンテンツ/機能を表示させます。コンテンツは、国・地域選択画面下部のボタンからもアクセスできます。

Cortellisを新しいタブ/ウィンドウで表示します。

Summary comparison | 規制要件の概要比較

- “Summary”では、Home pageで選択した国・組織におけるCMC要件の概要を比較表形式で確認できます。
- この表示では、特定のトピックについて複数の国での規制要件を一覧することが可能です
- この画面の例では、“Marketing Authorization Application Requirements > Licenses & Certificates”を選択しています。

Cortellis CMC Intelligence | Small Molecules

Home Pageで選択した国: China, India, Pakistan

選択した規制トピック: Licenses and certificates

Excelへの出力: EXPORT (New)

My selection	Application form	Proof of payment	Brand name clearance	Free sale certificate	GMP certificate	Submission of QOS	Business license	Manufacture license
China	✓	✓	✓	Not specified	✓	✓	✓	✓
India	✓	✓	✓	✓	✓	✓	✓	✓
Pakistan	✓	✓	Not specified	✓	✓	✓	✓	✓

規制のトピック一覧から確認したい項目を選択

Home pageで選択した国について要件を比較可能

Detailed Requirements comparison | 詳細要件比較（リスト表示）

- Home pageで選択した国や組織の規制要件の詳細について、リスト表示（List View）または並列表示（parallel View）で比較できます
- 初期表示はリスト表示です
 - この画面の例では、“CMC Requirements – Drug Substance > Impurities > General Information”について、Chinaの要件を表示しています

選択されている国

表示しているトピック

並列表示への切替

Change View: [List View] [Parallel View]

Local Practice [x] Null Results [x]

Official Regulations:
各国規制当局によって定められた規制要件の詳細を記載

Official Regulations

3.2.S.3.2 Impurities:

- List all impurities that products may contain (including organic impurities, inorganic impurities, and residual solvents and catalysts).
- Provide detailed impurities profile including the origin of impurities.
- Analyze the source of impurities (synthetic raw materials brought in by-products generated during the production or degradation generated) and provide control limits. Example: For the degradation products, explain using accelerated stability and strong degradation test.
- Provide the basis for whether there is control in the final quality standards and control limits.
- Provide structure verification information for known impurities.
- Possible genotoxic impurities shall be analyzed, investigated and controlled according to the preparation processes for the starting materials and this product.

Identification threshold, Reporting threshold

Local Practice:
各国コンサルタントによる、現地慣行に関する追加コメント

Local Practice

The limits for impurities should comply with Ch.P. If not in Ch.P. then follow the requirements in the general chapter. Frequently the standards are similar to that in ICH.

Product Type: FPP
Submission Type: New Drug, Generic Drug
Drug Type: Drug Substance
Pharmaceutical Form: Not Applicable
Procedure: Standard Procedure, Accelerated Procedure
Country of Origin: Local, Foreign

SourceID: [18](#), [35](#), [40](#), [408](#), [705](#)

04-May-2016
ICH Q3C (R2) Impurities in New Drug Substances
Submission Requirements
NMPA

Source IDをクリックすると
規制の情報源についてポップアップで表示します

各トピック名をクリックして
詳細要件を表示

各トピック名をクリックして
詳細要件を表示

Detailed Requirements comparison | 詳細要件比較（フィルター選択画面）

- フィルター機能を使用して、表示するCMC要件を一定の条件に従って絞り込むことができます。

“Filters”をクリックしてフィルター項目を表示

表示させたいCMC要件の条件を選択

全てのフィルター項目を見るにはスクロールしてください

最後に“Apply”をクリックしてフィルター条件を適用します

フィルター項目

- Product Type :
治験用医薬品 / 医薬品最終製品
- Submission Type :
新規医薬品/ジェネリック etc.
- Drug Type : 原薬 / 製剤
- Pharmaceutical Form : 剤型/投与経路
- Procedure : 申請方法
(標準審査、優先審査、WHO-PQ etc.)
- Country of Origin :
生産国 (現地・外国)

Detailed Requirements comparison | 詳細要件比較（フィルター適用後画面）

- 選択されたフィルター条件に従って、表示する規制要件が絞り込まれます
- 現地慣行“Local Practice”や、該当項目が無い場合“Null Results”の表示/非表示を切替えられます
- この画面では各国の要件がリスト表示（List View）になっています。国名をクリックすることで、その国の規制要件の表示エリアを広げたり、畳んだりできます。

Cortellis CMC Intelligence

選択中のフィルター項目

Local Results 表示/非表示
Null Results 表示/非表示

“Clear all”をクリックするとフィルターを全て一括解除できます

国名をクリックすると、その国の規制要件の表示エリアを開閉できます

Local Practice 表示/非表示
Null Results 表示/非表示

My selection (3)

Detailed Requirements

Clinical Trial Requirements

Marketing Authorization Requirements

CMC Requirements – Drug Substance

S.1 General Information

S.2 Manufacture

S.3 Characterization

S.3.1 Elucidation of Structure and other Characteristics

S.3.2 Impurities

General Information

Residual Solvents

Inorganic Impurities

Genotoxic Impurities

Organic Impurities

S.4 Control of Drug Substance

S.4.1 Specification

S.4.2 Analytical Procedures

S.4.3 Validation of Analytical Procedures

Official Regulations

S.3.2 Identification

Local Practice

No additional information available

Product Type: IMP
Submission Type: New Drug
Drug Type: Drug Substance
Pharmaceutical Form: Not Applicable
Procedure: Standard Procedure
Country of Origin: Local, Foreign

SourceID: 853

Pakistan

Detailed Requirements comparison | 詳細要件比較（リスト表示から並列表示への切替）

- 並列表示“Parallel View”では各国規制要件を横並びで表示できます
- 国の表示はアルファベット順です
- 任意の国の情報が常に一番左側に表示されるようピン止めすることができます
- リスト表示から並列表示に切替ても、表示中の規制トピックやフィルター設定は引き継がれます
- “Change View” ボタンでリスト表示に戻すことができます

The screenshot displays the Cortellis CMC Intelligence interface for comparing regulatory requirements. The sidebar on the left shows the navigation menu with the 'Detailed' view selected. The main content area displays regulatory requirements for three countries: China, India, and Pakistan. The 'Change View' button is located in the top right corner. Annotations highlight the 'Detailed' view selection, the 'Change View' button, and the pinning functionality for a country.

Annotations:

- 選択中の国の規制要件が横並びで表示されます
- リスト表示/並列表示の切替え
- Change View: [List View Icon] [Parallel View Icon]
- ピンのマークをクリックすると、その国の情報が常に一番左の列に表示されます

Detailed Requirements comparison | 詳細要件比較 (テキストフィルター機能)

- “Detailed”タブでは、フリーテキスト入力によるコンテンツフィルタ機能を使用できます
- 任意のテキストが含まれるコンテンツだけにコンテンツ表示を絞り込むことができます
- 単一キーワードおよび複数単語で構成されるフレーズどちらにも対応します

The screenshot displays the Cortellis CMC Intelligence interface for Small Molecules. The left sidebar shows navigation options: Home, Summary, Detailed (highlighted with a purple arrow), Report, Alerts, Ask the Expert, and Cortellis. The main content area is titled 'General Information' and shows search results for 'bioequivalence'. A search bar at the top contains the text 'bioequivalence' and a 'Search applied' button. Below the search bar, there are filters and two columns of results for 'China' and 'India'. The 'China' column shows 'Official Regulations | FPP' and 'P.2.2.1 - Formulation Development'. The 'India' column shows 'Official Regulations | FPP'. A purple box highlights the search bar with the text '画面上部のフリーテキスト入力欄に 任意のキーワードやフレーズを入力します'. Another purple box highlights the 'General Information' section in the sidebar with the text '指定したテキストを含むセクションだけに表示が絞り込まれます'. A third purple box highlights the word 'bioequivalence' in the search results with the text '指定したテキストが含まれる部分が 黄色でハイライトされます'.

Cortellis CMC Intelligence | Small Molecules

Home
Summary
Detailed
Report
Alerts
Ask the Expert
Cortellis

▼ CMC Requirements – Drug Substance

▼ S.4 Control of Drug Substance

S.4.4 Batch Analyses

▼ CMC Requirements – Drug Product

▼ P.2 Pharmaceutical Development

▼ P.2.2 Drug Product

▼ P.2.2.1 Formulation Development

General Information

Bioequivalence

BE waivers

Essential similarity

Dose dumping

P.2.3 Manufacturing process development

▼ P.5 Control of Drug Product

P.5.4 Batch analyses

P.5.5 Characterisation of Impurities

General Information

Search Detailed Requirements...
bioequivalence

Search applied

Filters

China < 1 of 2 >

Official Regulations | FPP

P.2.2.1 - Formulation Development

Refer to "Technical guidelines for chemical drugs studies"

information (including formulation design, formulation screening and optimization, formulation confirmation and other studies), and the results of quality characteristics in comparative study with the control drugs (need to explain the source of the control drugs, batch and expiration date, self-research sample batch, comparative project, methodology), and high changes in the drug development studies that support the excess feed in product necessity and rationale of excess feed.

2017 update: In 2016, China introduced retroactive requirements for specified generic drugs to establish bioequivalence against innovator, with the previous use of local comparator no longer sufficient. Comparison studies include formulation, quality standard, crystal form, particulate size, impurities and dissolution profile and in vivo BE studies.

India < 1 of 3 >

Official Regulations | FPP

A brief summary describing the development of the drug product should be provided, taking into consideration the proposed route of administration and usage. The differences between clinical formulations and the formulation (i.e. composition) described in 3.2.P.1 should be discussed. Results from comparative in vitro studies (e.g., dissolution) or comparative in vivo studies (e.g., bioequivalence) should be discussed when appropriate.

Points provided for CMC may or may not be included in guidelines but considered based on experience and ICH requirements. As India is one of the observer countries of ICH and follows ICH requirements.

It may be possible to convince agency on submission with appropriate justification for acceptance of foreign data and submission of data during review.

This may be granted case to case basis based on the unmet medical need. It's always advisable to go with full set of tests in line with EU/US requirements for smooth submission/approval of application.

Change View: [List View] [Table View]

Local Practice ☒ Null Results ☐

Reports | Overview/Key Facts (概要ページ)

- 個々の国・地域・組織の規制要件に関するレポートを表示します
 - 表示項目: Key Facts, Key Requirements, Procedures, Detailed Requirements, Sources, Change History
 - “Report”画面の初期表示は“Key Facts”です

Key Facts

- 表示中の国の規制対応に影響を与える重要かつ特異的な事柄について現地のエキスパートが解説します

The screenshot displays the 'Reports' section of the Clarivate Analytics platform. The interface is divided into a left sidebar, a top navigation bar, and a main content area. The sidebar contains a 'My selection (3)' dropdown with 'China', 'India', and 'Pakistan'. Below this is a list of report types: 'Key Facts' (highlighted with a blue box and an arrow), 'Key Requirements', 'Procedures', 'Detailed Requirements', 'Sources', and 'Change History'. The top navigation bar shows the 'China' selection and a 'Last Change Date 28-May-2019' indicator. The main content area displays the 'Key Facts' for China, including a summary of regulatory changes and a list of bullet points. Annotations with arrows point to various elements: '表示する国・地域の選択' points to the 'My selection (3)' dropdown; '現在選択中の国名' points to the 'China' selection; '各国レポートはPDFまたはExcel形式で出力可能' points to the 'Export Requirements Report to PDF' and 'Export Detailed Requirements to Excel' buttons; '当該国のレポートの最終更新日を示しています' points to the 'Last Change Date 28-May-2019' indicator; and '“Report”内のコンテンツ切替え' points to the 'Key Facts' report type in the sidebar.

表示する国・地域の選択

現在選択中の国名

China

Export Requirements Report to PDF

Export Detailed Requirements to Excel

各国レポートはPDFまたはExcel形式で出力可能

Last Change Date 28-May-2019

当該国のレポートの最終更新日を示しています

Key Facts

Key Requirements

Procedures

Detailed Requirements

Sources

Change History

“Report”内のコンテンツ切替え

CFDA - China medicine agency name has now been changed as **NMPA** (National Medicinal Products Administration) from July 2018.

Chinese regulations are evolving rapidly, particularly core CMC DS / DP review processes (new drug classification in March 2016)

Regulations are becoming tighter and more aligned to ICH, US & EU. China became a full member of the ICH in 2017.

Local trials can be performed in all phases of clinical development (previously only Phase 2 and above) Review and drug control/testing can occur at both provincial and federal level during registration process. Provincial FDA (PFDA) is involved only when drug product is manufactured in China Local sample testing by NICPBP is always required; for locally manufactured drugs, NICPBP may appoint a provincial drug quality control institute For imported drugs the entire review process is done by CFDA

Drug marketing permit (DIL) required for API / excipients and FFP for marketing

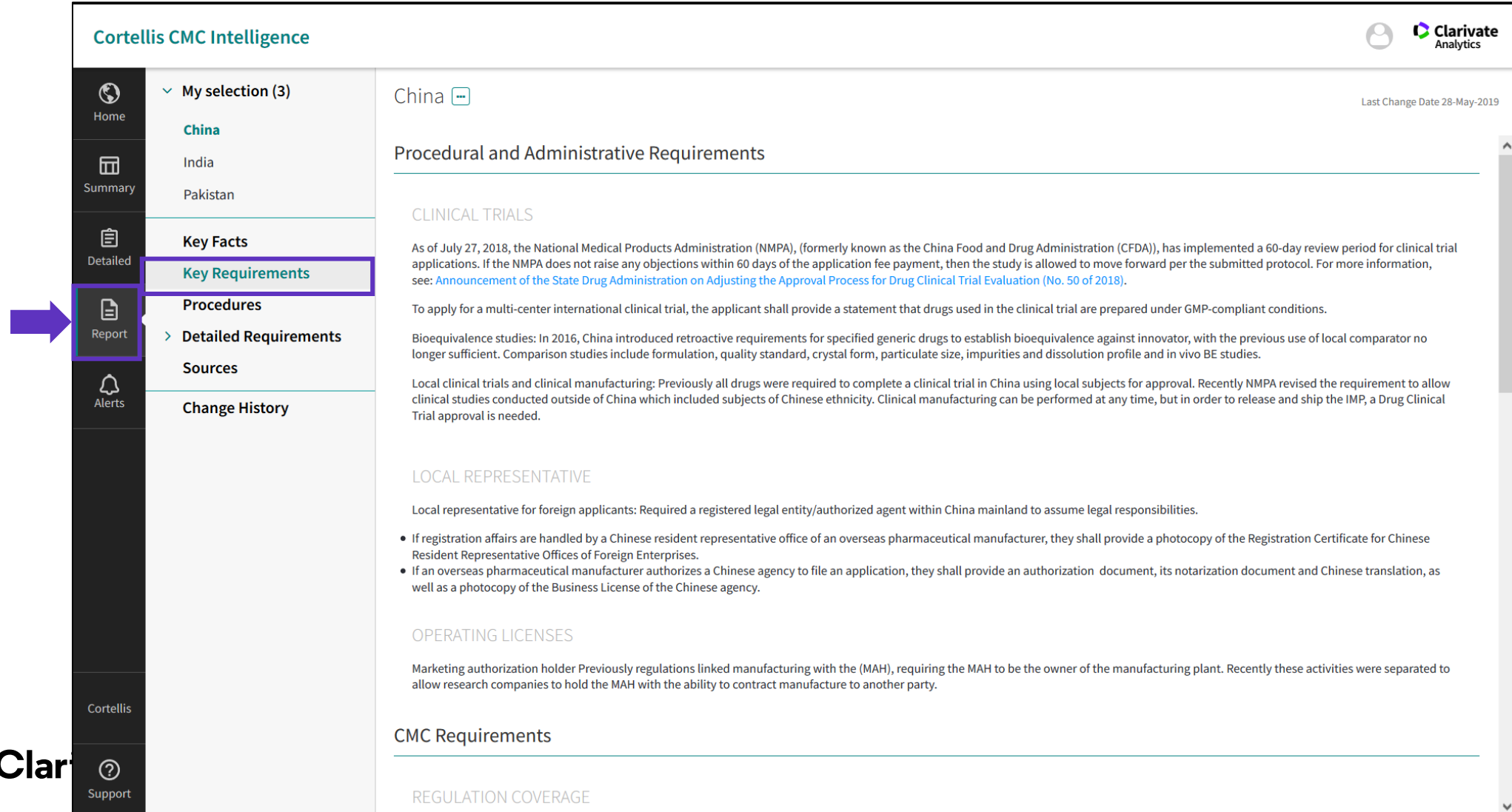
The "China Listed Drugs Collection" is the official website of the State Food and Drug Administration in the form of a web version and links to drug review reports, specifications, patent information and other databases.

- The State Food and Drug Administration will directly update the newly registered classified drugs and the drugs that have passed the evaluation of the quality and efficacy of generic drugs directly into the "China Listed Drugs Collection" and update them in real time.
- The carrier includes generic drugs approved for marketing, modified new drugs, generics registered in the new chemical classification, and specific information on drug evaluation through consistency in quality and efficacy.
- Designated reference preparations and standard preparations for generic drugs, indicating specific generic drug varieties that can replace the original research drugs, etc., for the pharmaceutical industry and medical professionals and the public to understand and inquire.

Reports | Key Requirements (主要な規制の枠組み)

Key Requirements

- 現在選択中の国における最新の規制情報や、重要あるいは特異的な要求事項について現地のエキスパートが解説します



The screenshot displays the Cortellis CMC Intelligence interface. On the left, a navigation sidebar includes icons for Home, Summary, Detailed, Report (highlighted with a purple arrow), Alerts, Cortellis, and Support. The main content area is titled 'China' and shows 'Procedural and Administrative Requirements'. It is divided into three sections: CLINICAL TRIALS, LOCAL REPRESENTATIVE, and OPERATING LICENSES. The CLINICAL TRIALS section includes text about NMPA's 60-day review period and a link to a 2018 announcement. The LOCAL REPRESENTATIVE section lists requirements for foreign applicants. The OPERATING LICENSES section discusses the separation of manufacturing and marketing authorization. The bottom of the page shows 'CMC Requirements' and 'REGULATION COVERAGE'.

Cortellis CMC Intelligence

Home Summary Detailed **Report** Alerts

My selection (3)
China
India
Pakistan

Key Facts
Key Requirements
Procedures
Detailed Requirements
Sources
Change History

China

Last Change Date 28-May-2019

Procedural and Administrative Requirements

CLINICAL TRIALS

As of July 27, 2018, the National Medical Products Administration (NMPA), (formerly known as the China Food and Drug Administration (CFDA)), has implemented a 60-day review period for clinical trial applications. If the NMPA does not raise any objections within 60 days of the application fee payment, then the study is allowed to move forward per the submitted protocol. For more information, see: [Announcement of the State Drug Administration on Adjusting the Approval Process for Drug Clinical Trial Evaluation \(No. 50 of 2018\)](#).

To apply for a multi-center international clinical trial, the applicant shall provide a statement that drugs used in the clinical trial are prepared under GMP-compliant conditions.

Bioequivalence studies: In 2016, China introduced retroactive requirements for specified generic drugs to establish bioequivalence against innovator, with the previous use of local comparator no longer sufficient. Comparison studies include formulation, quality standard, crystal form, particulate size, impurities and dissolution profile and in vivo BE studies.

Local clinical trials and clinical manufacturing: Previously all drugs were required to complete a clinical trial in China using local subjects for approval. Recently NMPA revised the requirement to allow clinical studies conducted outside of China which included subjects of Chinese ethnicity. Clinical manufacturing can be performed at any time, but in order to release and ship the IMP, a Drug Clinical Trial approval is needed.

LOCAL REPRESENTATIVE

Local representative for foreign applicants: Required a registered legal entity/authorized agent within China mainland to assume legal responsibilities.

- If registration affairs are handled by a Chinese resident representative office of an overseas pharmaceutical manufacturer, they shall provide a photocopy of the Registration Certificate for Chinese Resident Representative Offices of Foreign Enterprises.
- If an overseas pharmaceutical manufacturer authorizes a Chinese agency to file an application, they shall provide an authorization document, its notarization document and Chinese translation, as well as a photocopy of the Business License of the Chinese agency.

OPERATING LICENSES

Marketing authorization holder Previously regulations linked manufacturing with the (MAH), requiring the MAH to be the owner of the manufacturing plant. Recently these activities were separated to allow research companies to hold the MAH with the ability to contract manufacture to another party.

CMC Requirements

REGULATION COVERAGE

Reports | Procedures (申請・審査プロセス)

- 医薬品の申請・審査・承認プロセスの情報を表示します
(標準審査プロセスに加え、優先審査、ジェネリック医薬品、WHO-PQなどの情報を含みます)
- 標準審査プロセスはフローチャートで表示され、審査のタイムライン（当局の公式情報と実際に必要なおおよその期間）の情報を併せて提供します

Cortellis CMC Intelligence

Home | Summary | Detailed | **Report** | Alerts | Support

My selection (3)
China | India | Pakistan

Key Facts
Key Requirements
Procedures
Detailed Requirements
Sources
Change History

China

Regulatory Submission Procedures

STANDARD PROCEDURE
DOMESTIC and IMPORTED PRODUCT

CLINICAL PHU

Accelerated Procedure

Stringent Regulatory Authority Approved

WHO Prequalification

表示中の国における審査プロセス情報

クリックして標準審査フローチャートを拡大表示

Reports | Detailed Requirements (規制要件詳細)

- “Detailed Requirements”のリスト表示と同一のフォーマット でCMC要件の詳細を表示します。Official Regulationに加え、現地慣行“Local Practices”もカバーし、フィルター機能も使用可能です。
- この画面では単一の国の情報だけを表示します、並列表示の機能は使用できません
- 現地慣行“Local Practice”や、該当項目が無い国“Null Results” の表示/非表示切替え機能は使用できません

The screenshot displays the Cortellis CMC Intelligence web application. The sidebar on the left contains navigation links: Home, Summary, Detailed, Report (highlighted with a blue box and a red arrow), Alerts, Cortellis, and Support. The main content area is titled 'Cortellis CMC Intelligence' and shows a list of countries under 'My selection (3)': China (selected), India, and Pakistan. The 'Detailed Requirements' section is expanded, showing a list of requirements for China. The first requirement is 'P.1 Description and Composition of the Drug Product', which is highlighted with a red box. Below this, there are sections for 'Official Regulations' and 'Local Practice'. The 'Official Regulations' section contains a list of requirements, with the first item '1. Filtration, and list the formulation composition per unit/ product dose in tabular form, outline the function of each component in the formulation. Indicate if' highlighted with a red box. The 'Local Practice' section shows 'No additional information available'. A red box highlights the 'Filters' button, and a red box highlights the 'Official Regulations' section. A red box also highlights the 'Report' button in the sidebar.

現在表示中の
規制トピック

China

P.1 Description and Composition of the Drug Product

Filters

フィルタ
機能を開く

Official Regulations

1. Filtration, and list the formulation composition per unit/ product dose in tabular form, outline the function of each component in the formulation. Indicate if

Local Practice

No additional information available

Product Type: FPP
Submission Type: New Drug, Generic Drug
Drug Type: Drug Product
Pharmaceutical Form: Solid oral, Liquid oral, Liquid Injectable, Inhaler, Solid, Modified Release, Powder, Cream, Spray, Drops
Procedure: Standard Procedure, Accelerated Procedure
Country of Origin: Local, Foreign

SourceID: [18](#), [35](#), [40](#), [705](#)

Official Regulations

Reports | Sources (規制要件の情報源の確認)

- 各規制要件の情報源、参照文書をリスト化しています
- この画面から規制当局の公式文書やウェブサイトにアクセスでき、データベース内に記載されている規制要件について情報源を直接確認することができます

The screenshot displays the 'Sources' section of the Cortellis CMC Intelligence interface. The left sidebar shows navigation options: Home, Summary, Detailed, Report (highlighted with a purple arrow), and Alerts. The main content area is titled 'Thailand' and lists regulatory sources. Annotations with arrows point to specific features:

- 文書の発出日、発出元機関別などの並べ替えできます** (You can sort by document issue date, issuing agency, etc.): Points to the 'Sort By' dropdown menu.
- 文書の発出日、タイトル、情報源の種類（規制当局の名称など）、Source ID、IDRAC番号（Cortellis Regulatory Intelligenceの文書と連携している場合）** (Document issue date, title, information source type (regulatory agency name, etc.), Source ID, IDRAC number (when linked with Cortellis Regulatory Intelligence documents)): Points to the first source entry.
- “Get PDF”をクリックして規制文書をダウンロードできます** (You can download regulatory documents by clicking “Get PDF”): Points to the 'GET PDF' button for the second source.
- この規制文書が収録されているウェブサイトの該当ページを開きます** (Opens the corresponding page of the website where this regulatory document is included): Points to the external link icon for the third source.
- IDRAC番号のリンクをクリックして、規制文書をCortellis Regulatory Intelligence内で開きます** (Click the IDRAC number link to open the regulatory document within Cortellis Regulatory Intelligence): Points to the IDRAC number link for the fourth source.

Table of Sources:

Date	Title	Source	IDRAC Number	Source ID	Status
26-May-2020	Recommendations and guidelines for conducting clinical drug research During the outbreak of the Coronavirus infection (COVID-19)	Thai-FDA		2795	Valid
28-Apr-2020	Procedures for Evaluation of Applications related to Drugs during the COVID-19 situation.	Thai-FDA	311340	2664	Valid
17-Sep-2018	GUIDELINE FOR MANUFACTURE OF IMP DRUGS FOR CLINICAL TRIALS IN THAILAND- PHOR YOR 8	Thai-FDA	288380	1315	Valid
08-Aug-2018	ASEAN GUIDELINE ON STABILITY STUDY OF DRUGS	Association of Southeast Nations (ASEAN)	285696		

Reports | Change History (更新履歴)

- “Change History”では、現在表示中の国のレポートの更新履歴を確認できます
- 更新履歴は更新日が最近のものを上位に表示します

The screenshot shows the 'Cortellis CMC Intelligence' interface. On the left, a sidebar contains navigation links: Home, Summary, Detailed, Report (highlighted with a purple arrow), and Alerts. The main content area is titled 'Change History' and displays a table of updates. Annotations in Japanese are present: a box points to the 'Report' link in the sidebar, another points to the 'Change History' section header, and a third points to the table. A fourth box points to the 'Event Type' column header, and a fifth box points to the 'Description' column header. The table lists various updates with columns for Date, Event Type, and Description.

Cortellis CMC Intelligence

My settings

Key Facts

Key Requirements

Procedures

Detailed Requirements

Sources

Change History

Report

Alerts

Cortellis

Support

Change History

Date	Event Type	Description
29-May-2019	Summary Requirements	CMC Requirements - Long-term Stability - Drug Product was updated
28-May-2019	Summary Requirements	CMC Requirements - Accelerated Stability - Drug Product was updated
28-May-2019	Summary Requirements	CMC Requirements - Long-term Stability - Drug Product was updated
04-Apr-2019	Summary Requirements	CMC Requirements - Appendices - Adventitious Agents was updated
04-Apr-2019	Detailed Requirements	CMC Requirements - Appendices - Novel Excipients was updated
04-Apr-2019	Detailed Requirements	CMC Requirements - Appendices - Solvents for Reconstitution and Diluents was updated
04-Apr-2019	Detailed Requirements	CMC Requirements - Regional information - Certificate of Suitability was updated
04-Apr-2019	Detailed Requirements	CMC Requirements - Regional information - Medical Device was updated
04-Apr-2019	Detailed Requirements	CMC Requirements - Regional information - Additional Information was updated
04-Apr-2019	Detailed Requirements	Procurement and Organizations requirements - Administrative Requirements - Candidates Eligibility was updated
04-Apr-2019	Detailed Requirements	Procurement and Organizations requirements - Administrative Requirements - Declarations and Certificates was updated
04-Apr-2019	Detailed Requirements	Procurement and Organizations requirements - WHO working groups and STGs FPP was updated

Clarivate Analytics

Last Change Date 28-May-2019

更新されたコンテンツ種別を確認できます

Cortellis CMC Intelligenceのコンテンツが更新された日付

コンテンツ内のどのトピックが更新されたのか確認できます

Export | 各国規制要件のPDFまたはExcelへの出力

- 各国のSummary, Detailed Requirementsの記載事項をPDFまたはExcel形式で一括出力できます

The screenshot displays the Cortellis CMC Intelligence Biologics interface. On the left, a sidebar contains navigation options: Home, Summary, Detailed, Report, Alerts, and Cortellis. The 'Report' option is highlighted with a blue box and a blue arrow pointing to it. The main content area shows the 'Brazil' entry under 'My selection (1)'. A blue box highlights the 'Export Requirements Report to PDF' and 'Export Detailed Requirements to Excel' options. A blue arrow points from a text box to the '...' icon next to the 'Brazil' entry. The text box contains the following text: "Report"タブでデータを出力したい国を表示させ、国名の隣の「…」アイコンをクリックすると、Exportメニューが表示されます。PDFまたはExcel形式での出力に対応しています。 The main content area also displays the 'Key Facts' for Brazil, including information about the Brazilian Health Regulatory Agency (ANVISA) and its role in regulating and implementing controls relating to production and commercialization, import, export of all the products subjects to the Brazilian Sanitary Surveillance System, including pharmaceutical products (API, FPP), cosmetics, food supplements, devices, tobacco and sanitizer products and other products that may products involving the possibility of health risk. ANVISA is structured into 5 directories and further subdivided into several management areas, which are defined in RDC 255/2018 and its revisions. The registration of medicinal products is responsibility of the General Office for the Evaluation of Medicinal products (GGMED). The analysis of the documentation related to the Pharmaceutical Technology of a registration process for a new, generic or similar medicinal product is accredited by the Office Responsible for the Evaluation of Technology Quality Assessment of for the Registration of Synthetic Medicinal Products (GQRMED). ANVISA in the past decade has expended its international participation in bilateral, regional and multilateral forums that discuss regulatory harmonization and convergence processes. ANVISA became a regulatory member of ICH in November 2016 and in November 2019 was elected to be part of ICH's Management Committee. With its participation in ICH, ANVISA is in the process of implementing some of the ICH guidelines, as the medical dictionary MEDRA and the Common Technical Document, for the formatting of Dossiers (see Guide 24 from August 2019). ANVISA has also applied to become part of the Pharmaceutical Inspection Co-operation Scheme (PIC/s) which has lead to the review of the Brazilian Good Manufacturing Practices regulation in 2019, with the issuance of RDC 301 and a series for normative instructions that details procedures for specific activities and types of medicinal products (see IN 35 to 48). Brazil has also been is an active member of MERCOSUR, as Argentina, Paraguay, Uruguay, Venezuela (suspended). The MERCOSUR purpose is free trade and the fluid movement of goods, people, and currency; and is now a full customs union and a trading block. Even though ANVISA works on convergence of regulations with the Health Authorities that are part of Mercosur, to date country specific registration is required in each market and there are no reliance mechanisms in place among the countries; At the end of 2019, ANVISA published RDC 317/2019 extending the product registration validity from 5 to 10 years and also implemented different validities for products approved under conditional approvals (3 years validity). This regulation also specifies the documentation and procedure for renewals that must be submitted Product registration is valid for 5 years. A renewal must be done no later than 6 months prior to expiry.

Export | Summaryテーブルの出力

- Summaryテーブルの内容をExcel形式で出力できます

The screenshot displays the 'Cortellis CMC Intelligence | Small Molecules' interface. On the left, a navigation sidebar includes 'Home', 'Summary' (highlighted with a purple arrow), 'Detailed', 'Report', 'Alerts', and 'Ask the'. The 'Summary' section shows 'My selection (3)' with entries for China, India, and Pakistan. Below this, 'Summary Requirements' are listed, including 'Licenses and certificates'. The main content area, titled 'Licenses and certificates', features an 'EXPORT' button (highlighted with a purple box and labeled 'Excelへの出力') and a 'New' button. A table displays the status of various requirements for the selected countries. A purple arrow points from a text box to the table, indicating that the table's content can be exported to Excel.

My selection	Application form	Proof of payment	Brand name clearance	Free sale certificate	GMP certificate	Submission of QOS	Business license	Manufacture license
China	✓	✓	✓	Not specified	✓	✓	✓	✓
India	✓	✓	✓	✓	✓	✓	✓	✓
Pakistan	✓	✓	Not specified	✓	✓	Not specified	Not specified	✓

選択中の国およびトピックに従って画面に表示された"Summary"テーブルの内容と同じものをExcelフォーマットで出力できます

Alerts | アラート設定画面

- 新規アラートの設定や、過去に設定したアラートの管理ができます
- 設定済みのアラートは作成日順に一覧表示されます

The screenshot shows the 'Alerts' management page in the Cortellis CMC Intelligence system. The interface includes a sidebar with navigation options: Home, Summary, Detailed, Report, Alerts (highlighted with a blue arrow), Cortellis, and Support. The main content area displays a table of alerts with columns: Name, Date Created, Frequency, My Selection, Content Type, Alert Status, and Delete. Two alerts are listed: 'China 14:23 07-Jun-2019' and 'Canada 15:44 06-Jun-2019'. Annotations in Japanese provide instructions: 'CREATE ALERT' button, alert name editing, sorting by creation date, and status toggling. A detailed list of table items is provided at the bottom.

Cortellis CMC Intelligence

Alerts

“CREATE ALERT”ボタンをクリックすると、アラート設定ポップアップ画面が開きます

CREATE ALERT

Name	Date Created	Frequency	My Selection	Content Type	Alert Status	Delete
China 14:23 07-Jun-2019	07-Jun-2019	DAILY	China, India, Pakistan	Detailed Requirements: Clinical Trial Requirements, Marketing Authorization Requirements, CMC Requirements – Drug Substance, CMC Requirements – Drug Product, CMC Requirements – Appendices, CMC Requirements – Regional information, Procurement and Organizations requirements	Active	
Canada 15:44 06-Jun-2019	06-Jun-2019	DAILY	Canada, Russian Federation, USA, Bangladesh	Detailed Requirements: CMC Requirements – Drug Substance	Active	

アラート名称の編集ができます

設定済みのアラートが作成日順にリスト表示されます

アラートはオン (Active) 、オフ (Inactive) の切替ができます。アラートを削除しなくとも、一時的に停止することができます。

設定済みアラート一覧 表示項目

- *Name* – アラート名称（自動的に付与されます、任意の名称に変更可能です）
- *Date Created* – アラート設定日
- *Frequency* – アラート頻度（daily, weekly, monthly）
- *My Selection* – アラートの対象として選択されている国名一覧
- *Content Type* – アラート対象のコンテンツ
- *Alert Status* – アラートのActive / Inactive状態表示、Inactiveの場合はアラートメールは送信されません
- *Delete* – アラートを完全に削除します

Alerts | Create Alert (新規アラート設定画面 – My selection)

関心のある国・組織などを一覧から選択します

選択された国・組織などの名称が表示されます

注：Create Alert画面を開くとHome pageで選択した国や組織がMy selectionとして予め選択されています

“Next”をクリックし、アラート対象のコンテンツおよびアラート頻度を選択する画面に進みます

Alerts | Create Alert (新規アラート設定画面 – Content Type & Frequency)

Frequency – Alert頻度設定

- *Daily*
 - 毎日 日本時間 午前にアラートメールを送信します
- *Weekly*
 - 毎週 日本時間日曜日にアラートメールを送信します
- *Monthly*
 - アラート設定翌日に最初のアラートメールを送信し、過去1ヶ月の最新情報をカバーします
 - それ以降は30日おきにアラートが送信されます

更新情報のアラートを受け
取りたいトピックを選択し
ます

トピック選択について

アラートはトピックの大項目ごとに選択して設定できます。選択されたトピック項目のコンテンツに更新があるとアラートがeメールで送信されます

The screenshot shows the 'Create Alert' form with two main sections: 'Content Type' and 'Frequency'. The 'Content Type' section has a list of checkboxes: 'Key Facts', 'Key Requirements', 'Detailed Requirements' (checked), 'Clinical Trial Requirements' (checked), 'Marketing Authorization Requirements' (checked), 'CMC Requirements – Drug Substance', and 'CMC Requirements – Drug Product'. The 'Frequency' section has three radio buttons: 'DAILY' (selected), 'WEEKLY', and 'MONTHLY'. At the bottom, there are three buttons: '< Back', 'Cancel', and 'Create'.

アラートの送信頻度を選択します

“Create”をクリックしてアラート設定を確定します

Alerts | Email 形式

- アラートのeメールはこのメールアドレスから送信されます cmc.alerts@clarivate.com
- アラートメールに返信することはできません、ご質問等をお送りにならないようお願いいたします

設定されたアラート頻度によって表記が変わります

• Date : コンテンツ更新日
• Event Type : 更新種別
• Description : 更新内容

eメールメッセージ下部の'To unsubscribe...' からアラート設定をオフ (inactive) に変更することができます。
アラートを再開するにはCMC Intelligenceのアラート設定ページから操作してください。

Cortellis CMC Intelligence

Clarivate Analytics

5-Jun-2019

CORTELLIS CMC INTELLIGENCE ALERT

Your **DAILY** alert contains information that was updated on or after 04-Jun-2019

Name: Brazil 11:24 01-May-2019
Product: [Cortellis CMC Intelligence](#)
Owner: [redacted]
Contact: [redacted]

UPDATED - SINCE LAST ALERT

Canada

Date	Event Type	Description
04-Jun-2019	Detailed Requirements update	Clinical Trial Requirements - Administrative Requirements - Application Procedure was updated
04-Jun-2019	Detailed Requirements update	Marketing Authorization Requirements - Administrative Requirements - Registration Procedure was updated

If you need help, please contact your [local Customer Service team](#) | To unsubscribe, please click [here](#)

サポートメニューの表示（英語）

- ・ 画面右下の「？」マークをクリックするとサポートメニューが表示されます
- ・ 日本語でのサポートをご希望の方は、次頁のユーザーサポートサイトをご参照頂くか、カスタマーケアの窓口にご連絡ください

The screenshot displays the Cortellis CMC Intelligence web application. The top navigation bar includes the logo, a user profile icon, and the text 'Clarivate Analytics'. Below this, a secondary navigation bar lists 'Countries/Territories', 'Regions', 'Climatic Zones', and 'Organizations'. A left-hand sidebar contains icons for 'Home', 'Summary', 'Detailed', 'Report', and 'Alerts'. The main content area features a world map. Overlaid on the map are three callout boxes with Japanese text: 'Product updates' (告知コンテンツや機能のアップデートをお知らせします), 'Training resources' (本マニュアルの英語版やその他のサポート資料にアクセスできます), and 'Contact us' (弊社グローバルのサービス窓口への連絡窓口です。日本語でのサポートをご希望される方は次頁の日本国内のカスタマーサービスにご連絡ください。). On the right side, a 'Resources & updates' dropdown menu is open, showing links for 'Product updates', 'Training resources', and 'Contact us'. At the bottom right, a callout box with the text '“？”マークをクリックしてメニューを開きます' points to a circular icon containing a question mark.

Cortellis CMC Intelligence

Clarivate Analytics

Countries/Territories | Regions | Climatic Zones | Organizations

Home

Summary

Detailed

Report

Alerts

Cortellis

Product updates
コンテンツや機能のアップデートをお知らせします

Training resources
本マニュアルの英語版やその他のサポート資料にアクセスできます

Contact us
弊社グローバルのサービス窓口への連絡窓口です。
日本語でのサポートをご希望される方は次頁の
日本国内のカスタマーサービスにご連絡ください。

Resources & updates

Product updates

Training resources

Contact us

“？”マークをクリックしてメニューを開きます

ユーザーサポートの充実



基本編

- [Cortellis CMC Intelligence新規申請版ユーザーガイド](#)
- [Cortellis CMC Intelligence 市販後変更申請版ユーザーガイド](#)
- [データベース内の略語集](#)
- [Cortellis CMC Intelligence - Factsheet \(英語\)](#)

日本語サポートサイト

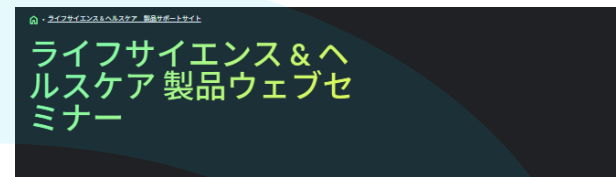
[Cortellis CMC Intelligence training resources | Clarivate](#)

日本スタッフによる日本語マニュアル・資料をご用意。



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いただけます。



2025

2025年6月19日 木曜日 11:00~12:00 (60分)
医薬品競争情報データベース Cortellis Competitive Intelligence 基本編トレーニングウェブセミナー

2025年6月19日 木曜日 13:00~13:50 (50分)
Cortellis Regulatory Intelligence入門編：世界の

2025年6月19日 木曜日 14:30~15:00 (30分)
疫学データベース Epidemiology Intelligence

2025年6月19日 木曜日 15:30~16:30 (60分)
Cortellis Drug Discovery Intelligence基本編：

2025年4月24日 木曜日 13:00~13:45 (45分)
基本編トレーニングウェビナー「Cortellis P

パブリックWebセミナー

<https://clarivate.com/life-sciences-healthcare/ja/training-support/training-calendar/>

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。

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
✉ lsh.support@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。