
Clarivate™
Optimizing Cortellis for labeling policy & strategy
Beth Wise| June 2024

# Agenda

30 mins + 15 mins Q&A

- Introduction
- Live demo
- Follow-up and Q&A

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# What is Cortellis Regulatory Intelligence?

Global regulatory information, across all functions and responsibilities

**290K+ official documents**

**8K+ value-add regulatory reports, analyses and global comparisons**

**All documents translated to English**

**81 countries and regions Drugs & Biologic and 75 Medical Devices & IVDs**

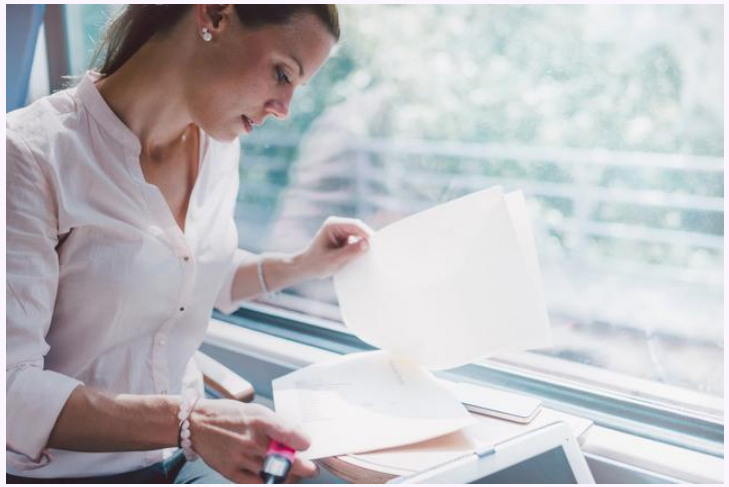
**Updated daily**

**Regulatory experts & local consultants**

# Scenario

I am responsible for labeling policy/strategy, and I need to:

1. Track US and EU labels by drug, disease, regulatory designation and more
2. Compare packaging and labeling requirements across multiple countries; for example, are Mandatory Warnings or Braille language required?
3. Discover curated reports providing the guidance I need on labeling policy plus link to source documents and English translations
4. Understand the competition – find approved drugs for thousands of indications globally



# Cortellis label coverage

Cortellis contains US and EU Labels because the FDA and EMA publish labels within their approval packages

- Approvals documents for these countries are also in Cortellis:
  - China, Japan, Singapore, Taiwan, Switzerland, Brazil, Canada and coming soon, UK

- Since labels are not included in these countries' approval documents, they are not included in Cortellis

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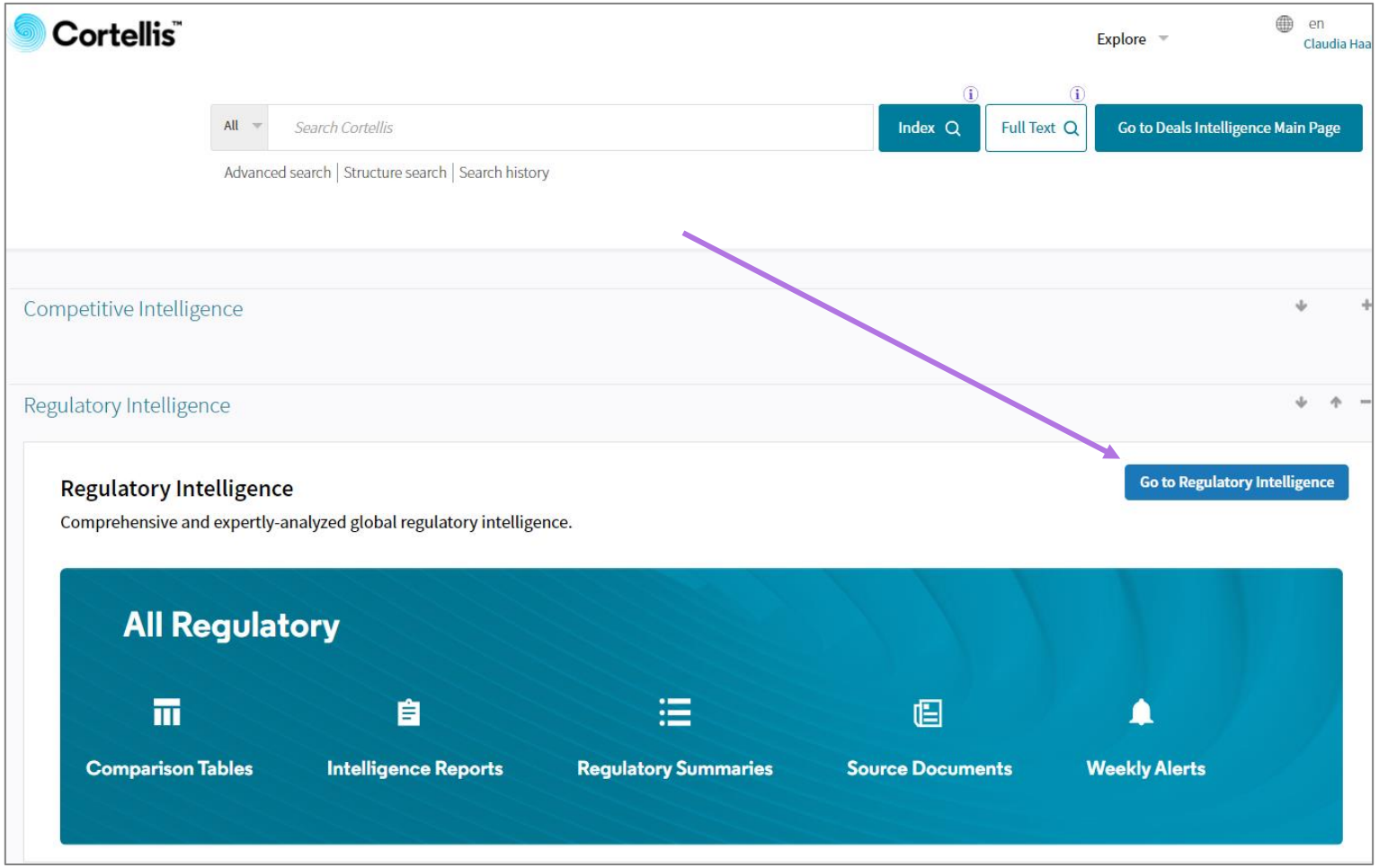
# Cortellis Landing Page

Click the "**Go to**…" button to access Cortellis Regulatory Intelligence

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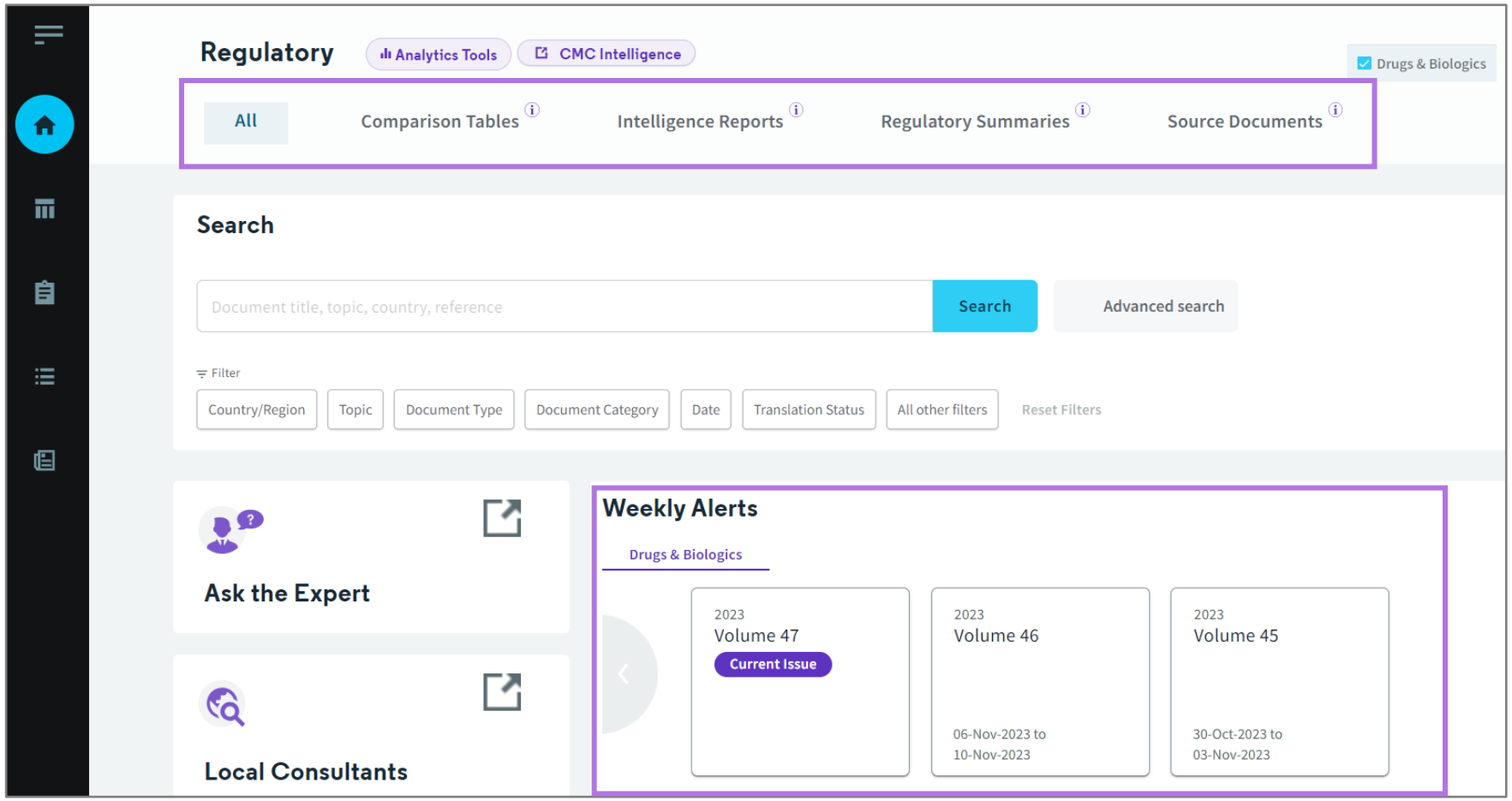
# Cortellis Regulatory Homepage

Start searching through all documents, click the tabs to browse value-add tables, reports and summaries or access the Cortellis Weekly Alerts newsletter.

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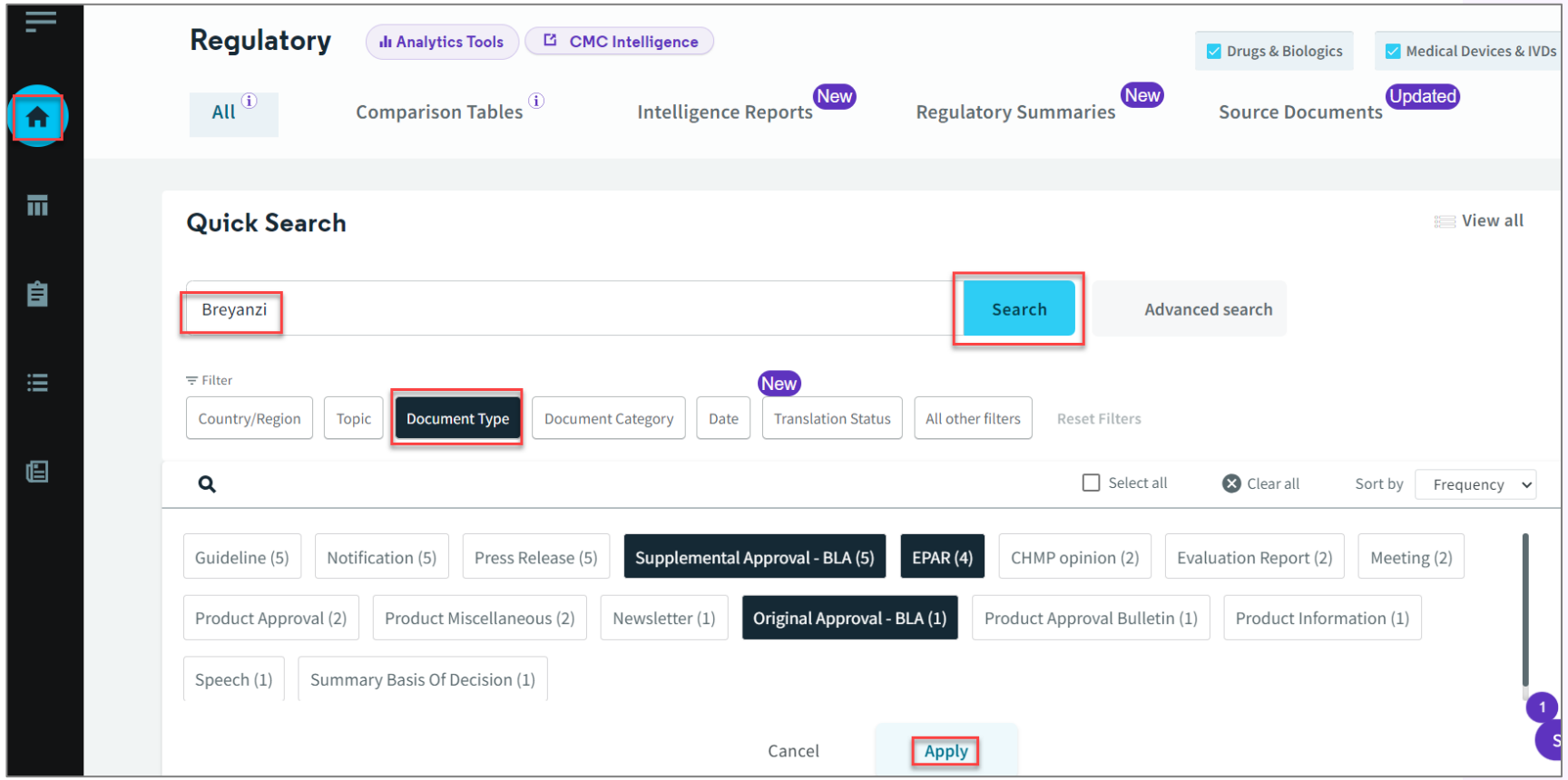
# Find US and EU labels by drug, disease, regulatory designation and more

## Quick Search – drug name




**Find US and EU labels for Breyanzi.**

1. Go to Quick Search on the Home Page

2. Type BRYANZI into the keyword search box

3. Select Document type filter and select the approval documents.

Breyanzi is a biologic so for the US select Original Approval – BLA and Supplemental Approval – BLA and for the EU, EPAR.

For small molecules in the USA choose Supplemental Approval – NDA and Original Approval - NDA

5. Click Apply and click Search

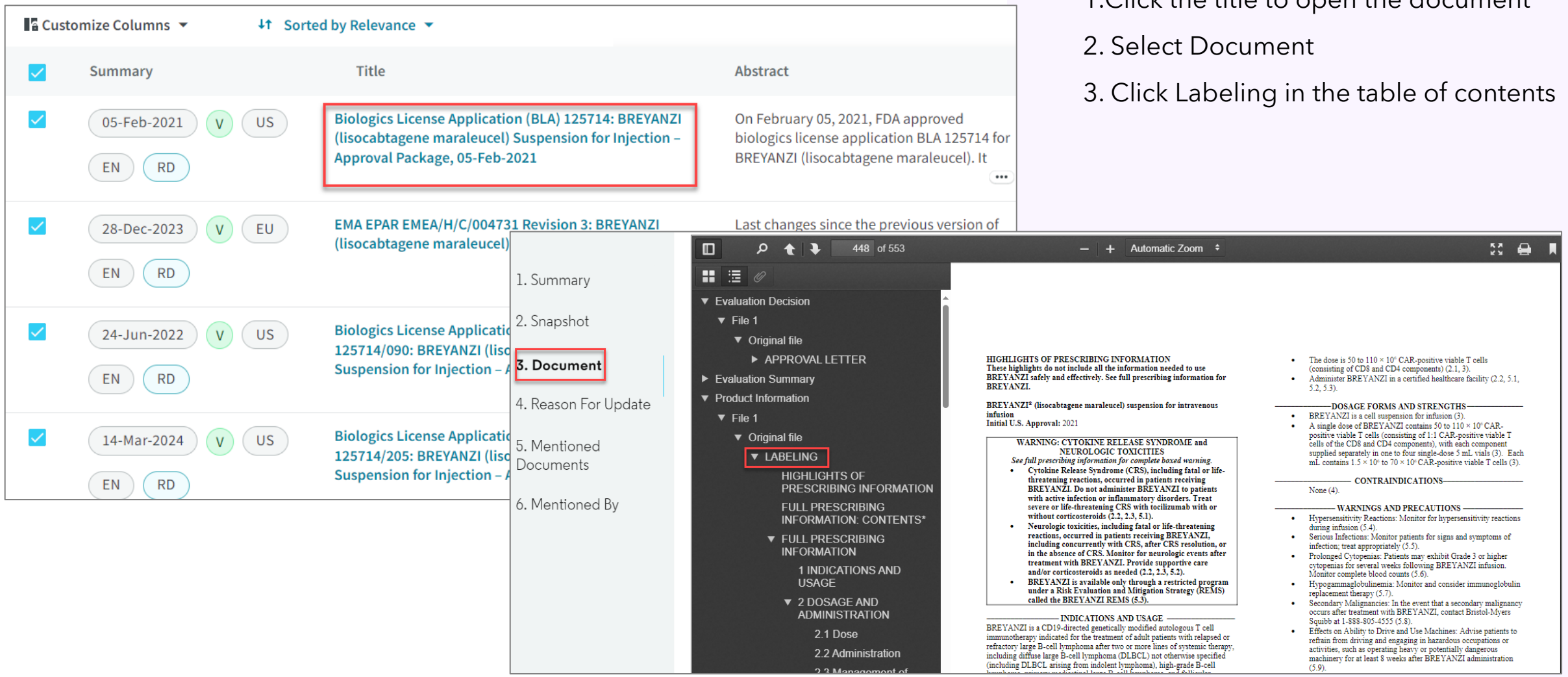
# Find US and EU labels by drug, disease, regulatory designation and more

## Quick Search – drug name

1.Click the title to open the document

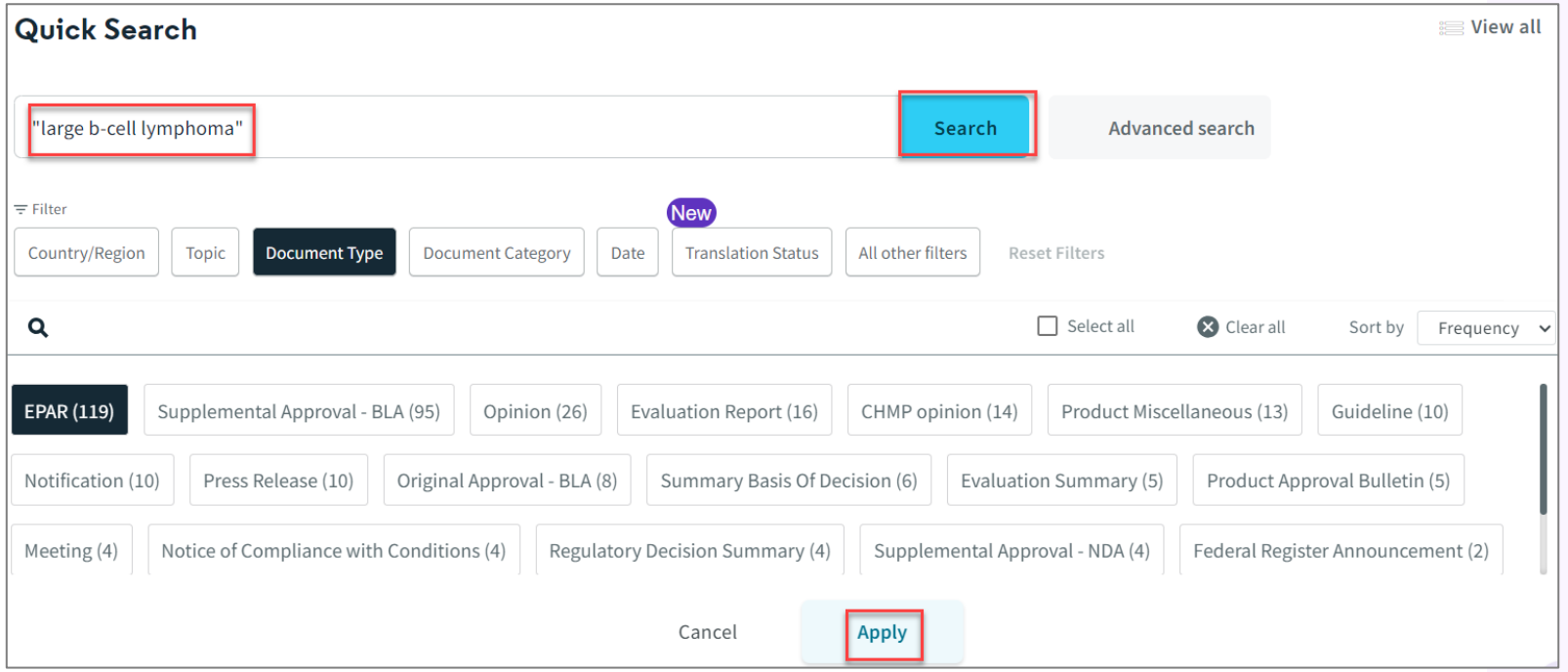
2. Select Document

3. Click Labeling in the table of contents



# Find US and EU labels by drug, disease, regulatory designation and more

## Quick Search – indication



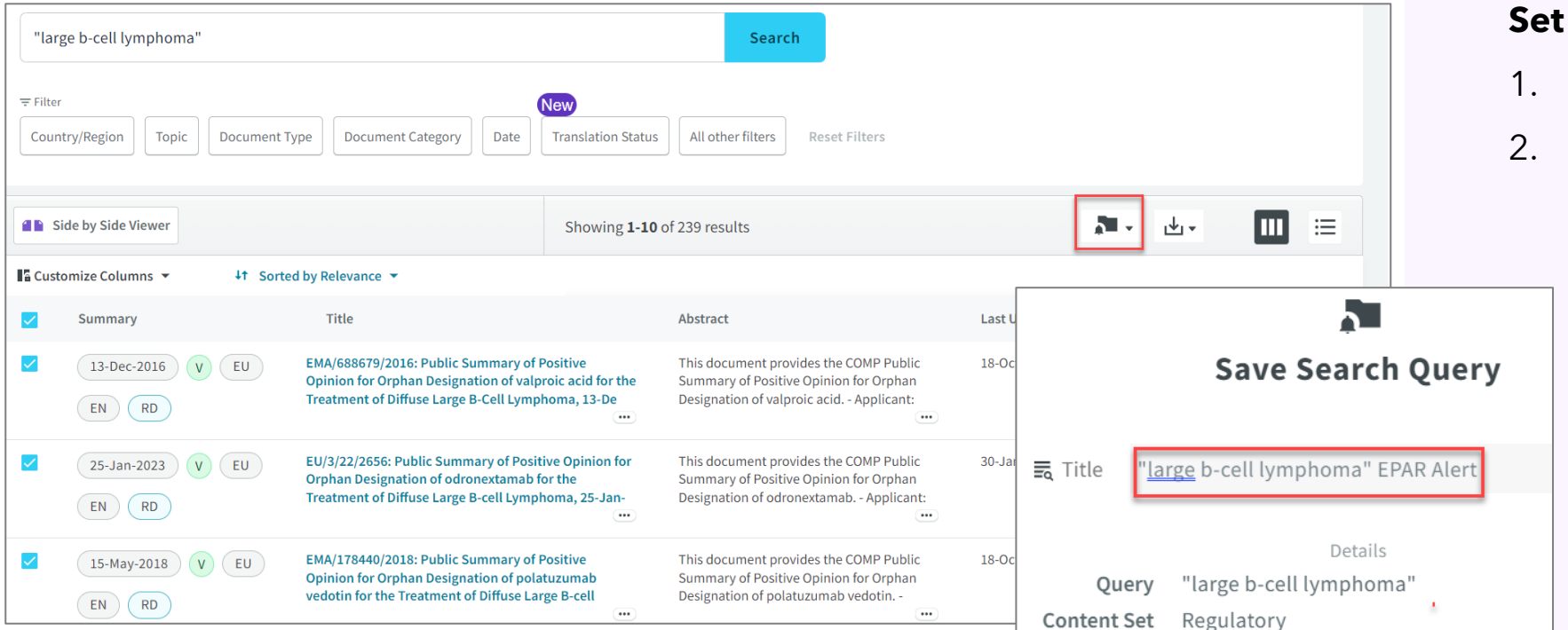

**Find all EPARs for an a disease/indication e.g., large b-cell lymphoma**

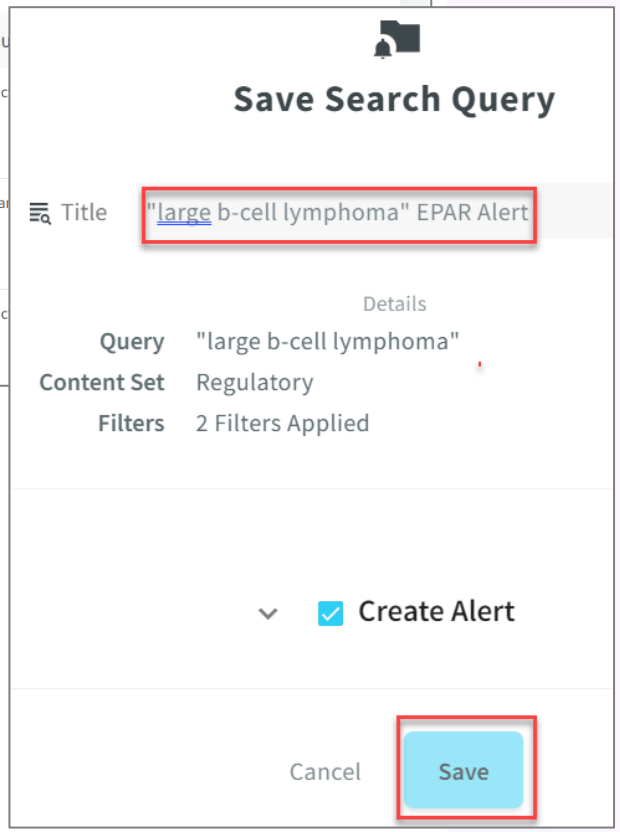
1. Type “large b-cell lymphoma” into the keyword box
2. Open Document Type folder and select EPAR
3. Click Apply and Search

Results found using Quick Search are very targeted as Quick Search only searches the Titles, Abstracts and Reason for Update sections of the whole report – not the entire document PDF.

# Find US and EU labels by drug, disease, regulatory designation and more

## Quick Search – indication




### Set up an Alert

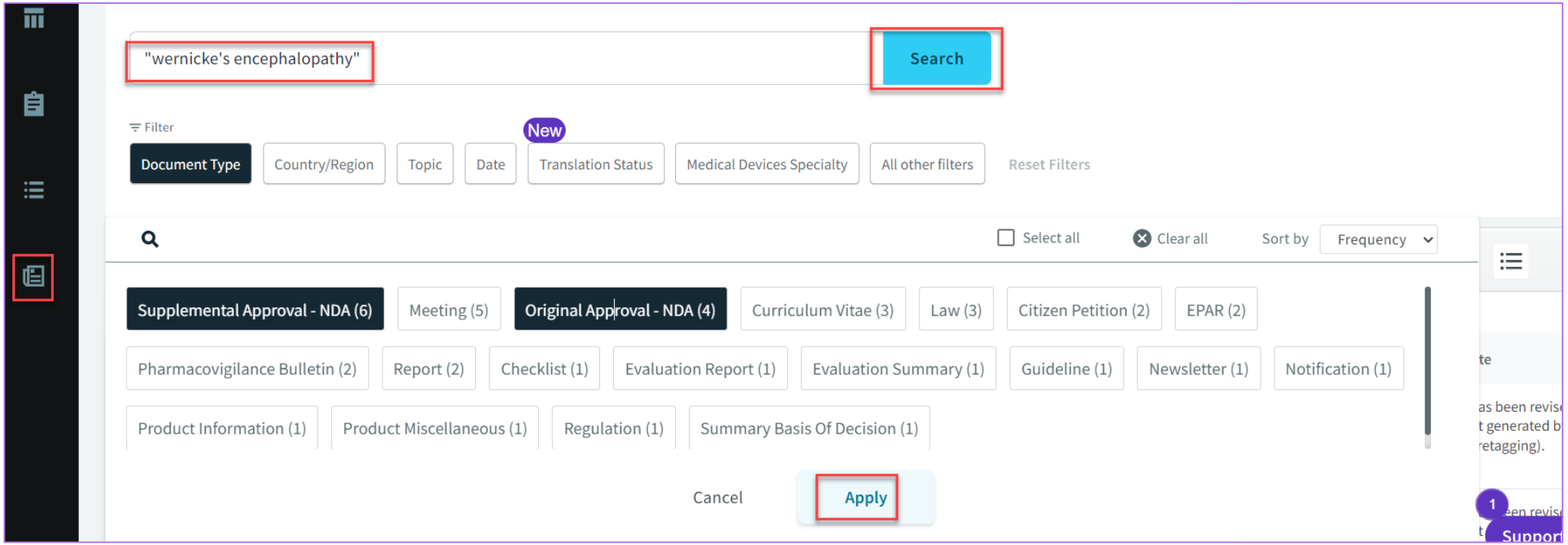
1. Click the Alert icon
2. Name the search in the pop-up and click Save

# Search entire documents – including labels

## Source Document Search

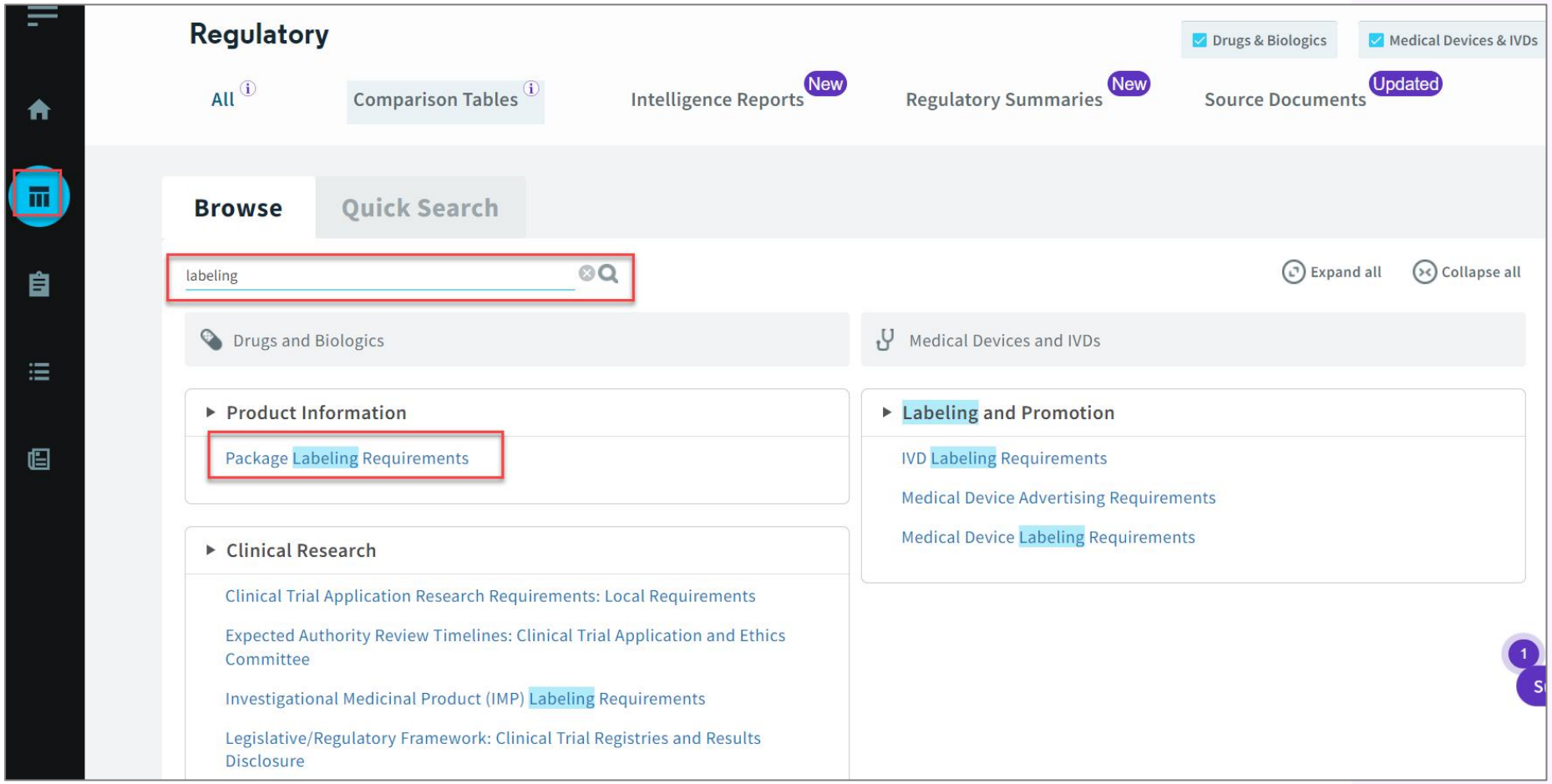
**Find all US Labels that mention Wernicke's encephalopathy**

1. Type "Wernicke's encephalopathy" into the keyword box
2. Select Document Type filter and Supplemental Approval – NDA and Original Approval – NDA
3. Click Apply and Search



# Compare packaging and labeling requirements across countries

## Comparison Tables

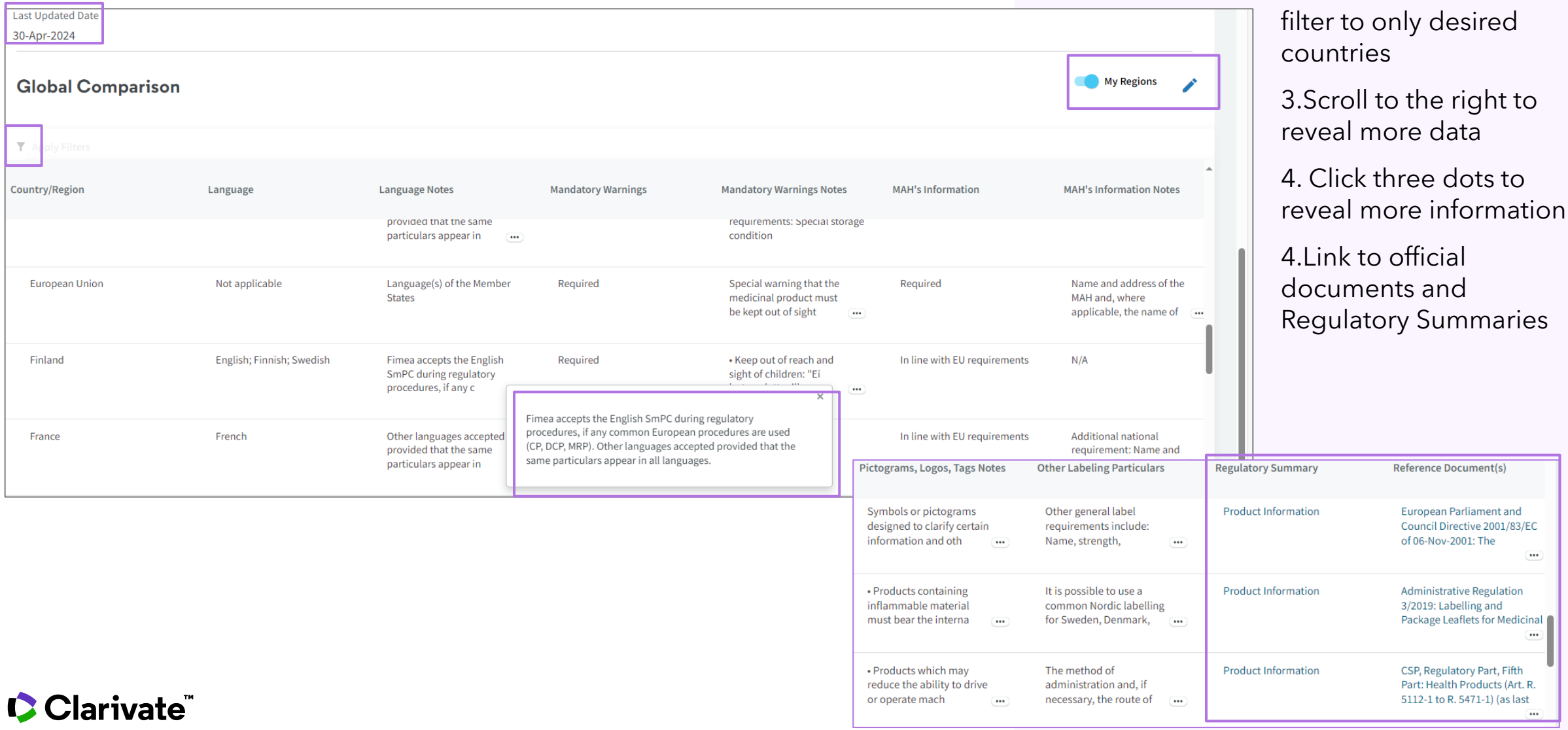



**Are Mandatory Warning and Braille Language required?**

1. Use the Filter tool to find the Comparison Tables with Labeling in the title
2. Choose Package Labeling Requirements

# Compare Package and Labeling Requirements

## Comparison Tables




1.Click the filter icon to filter to only desired countries

3.Scroll to the right to reveal more data

4. Click three dots to reveal more information

4.Link to official documents and Regulatory Summaries

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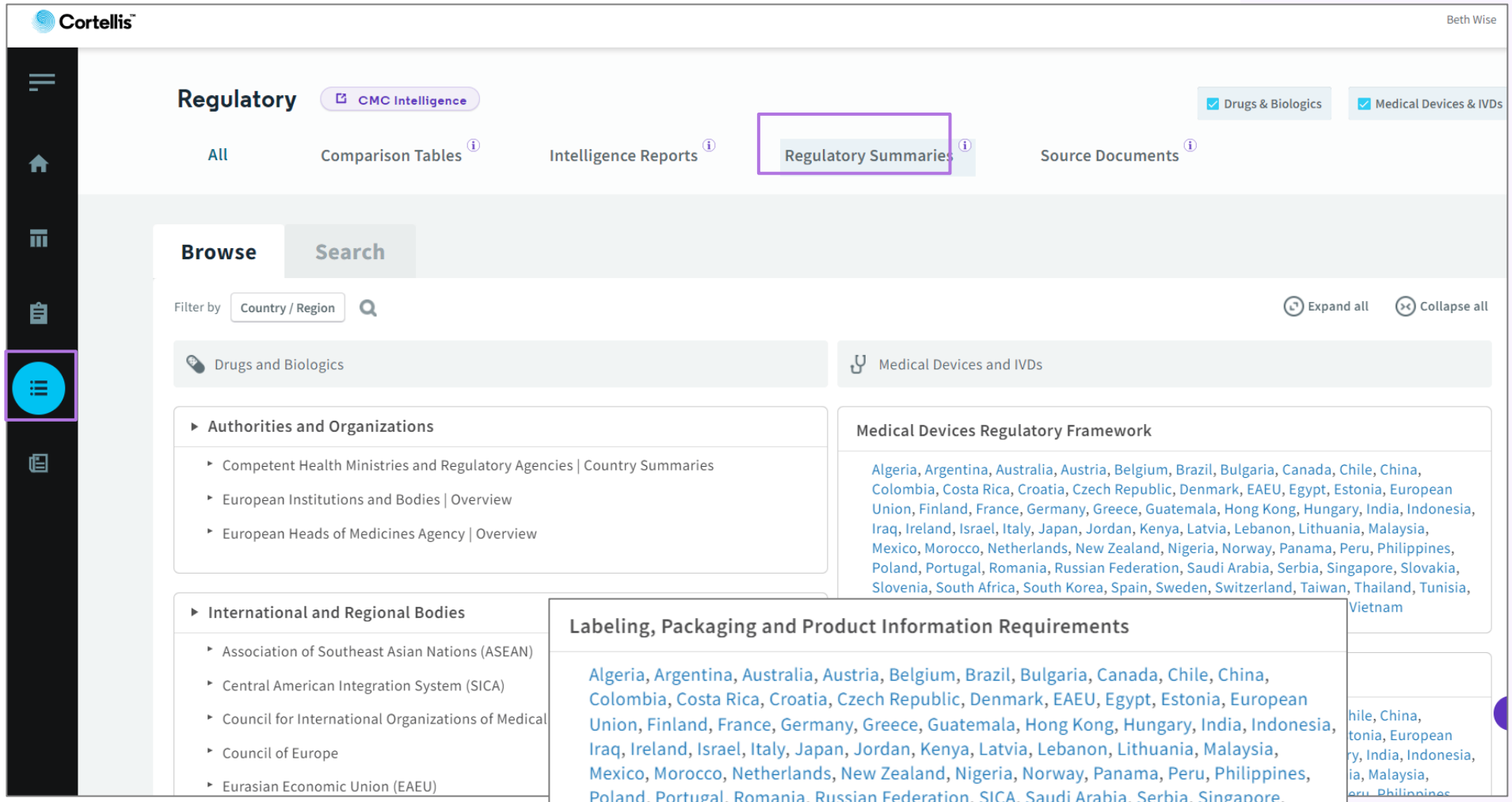
# Dive Deep into Labeling requirements for a country

## Regulatory Summaries



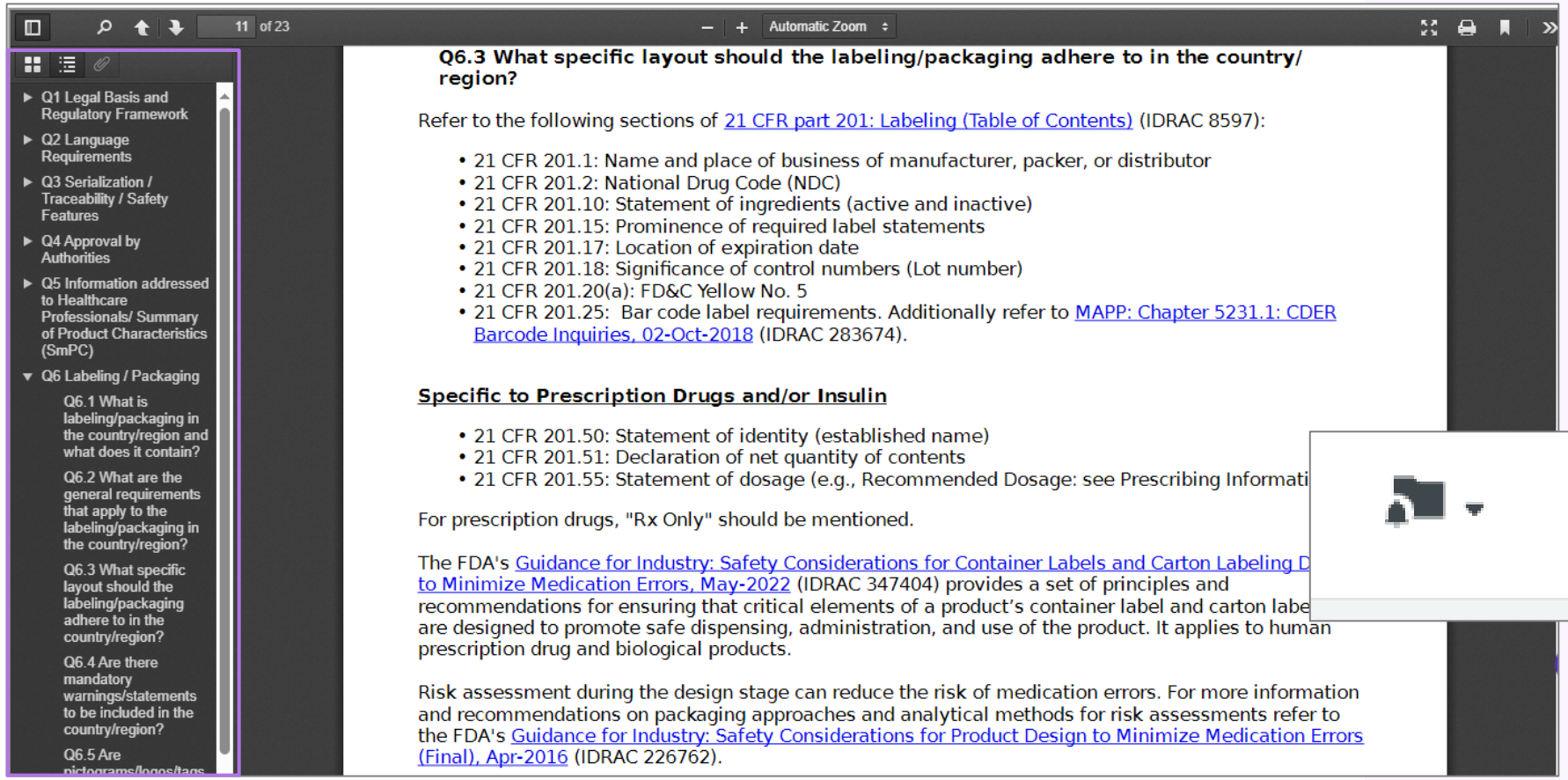

1.Click Regulatory Summaries

2.Scroll down to Labeling, Packaging and Product Information Requirements

3.Click your country, e.g.; USA

# Dive Deep into Product Information for a country

## Regulatory Summaries



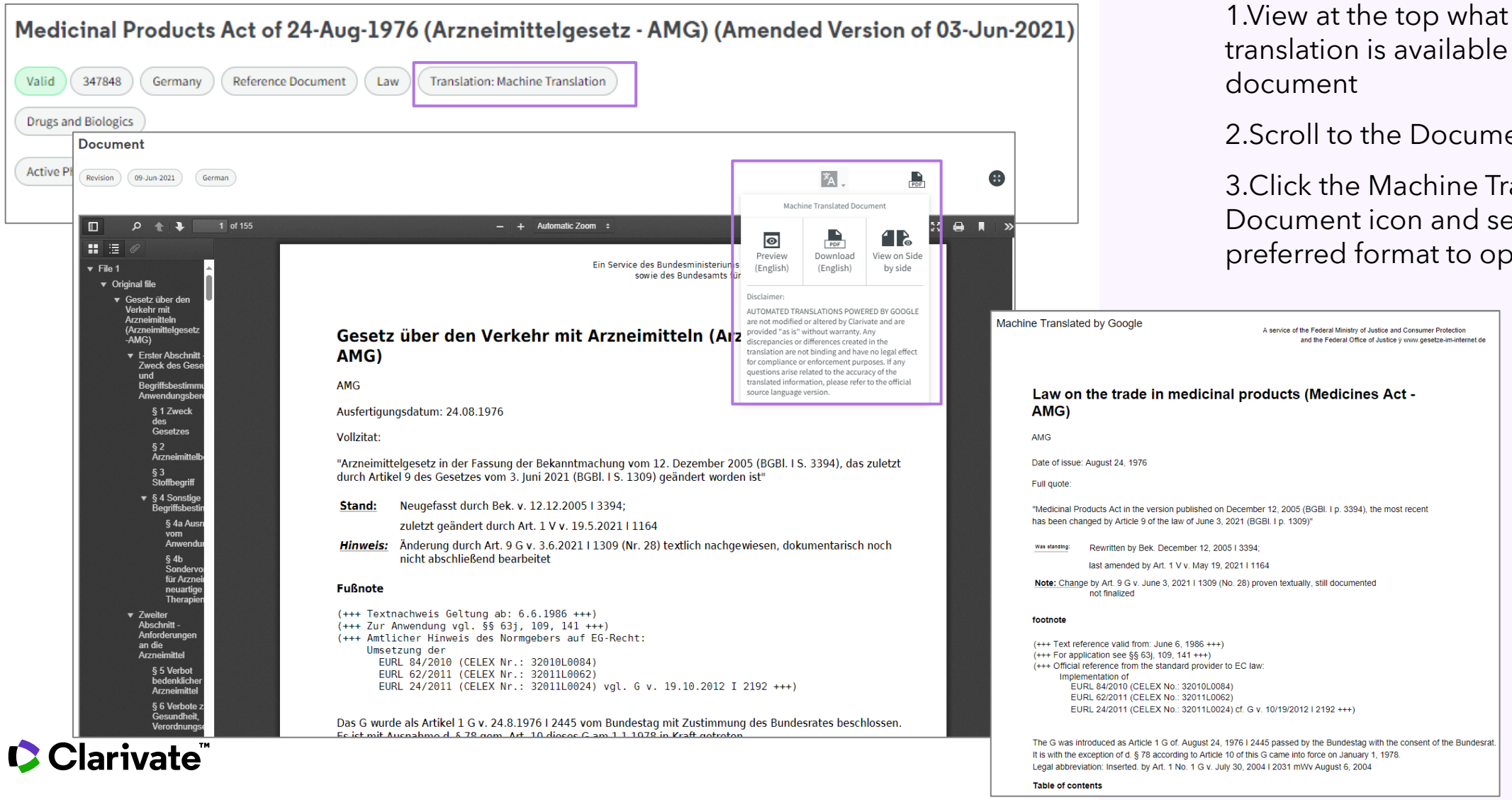

1.Consistent Q&A format across all countries/regions provides expert, consistent guidance for each country

2.Link to official documents

3. Export and set up Alerts from the icons in the upper right-hand corner

# English Translations of Source documents

## Machine Translations



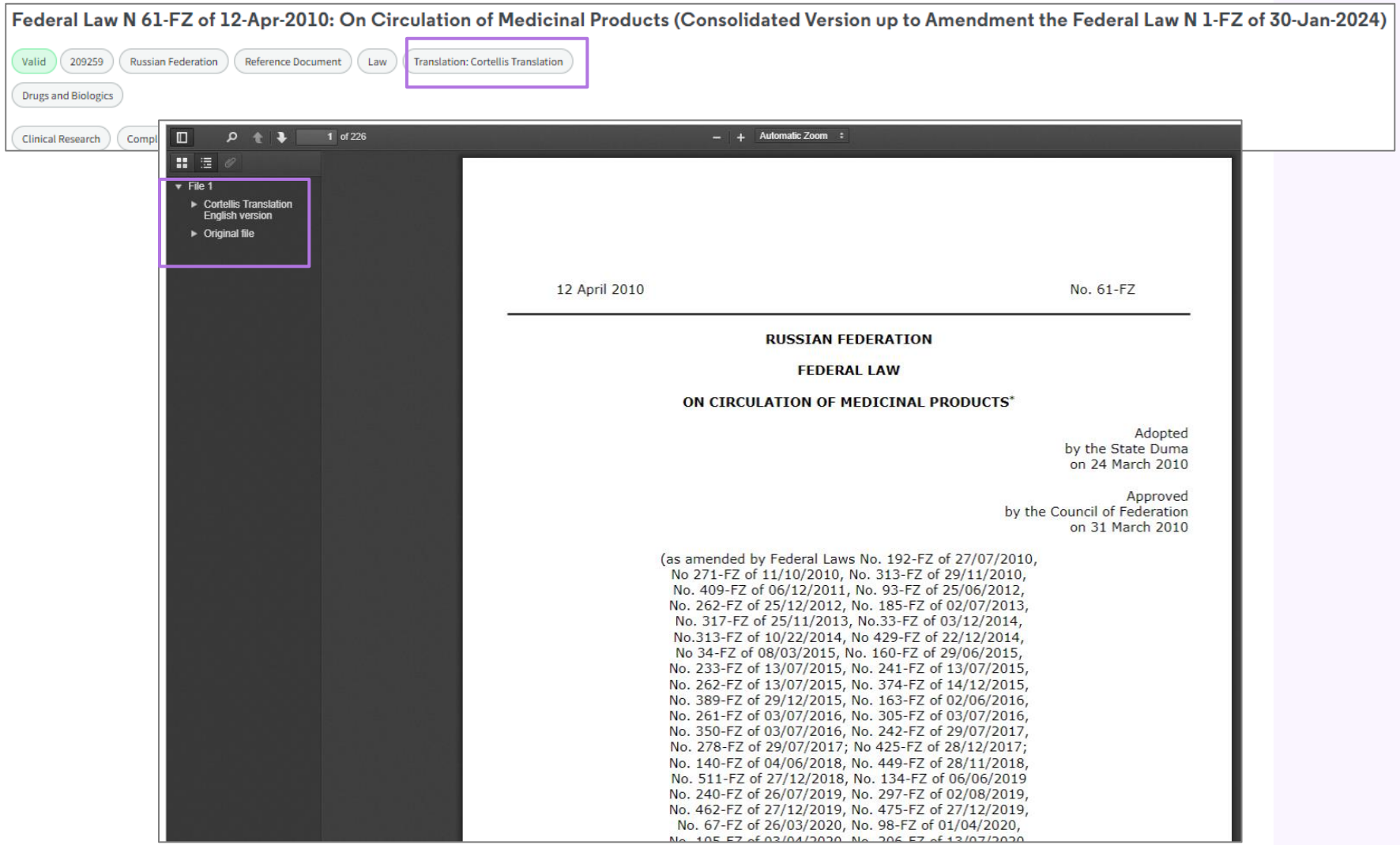

1.View at the top what type of translation is available for that document

2.Scroll to the Document

3.Click the Machine Translation Document icon and select preferred format to open

# English Translations of Source documents

## Human Translations



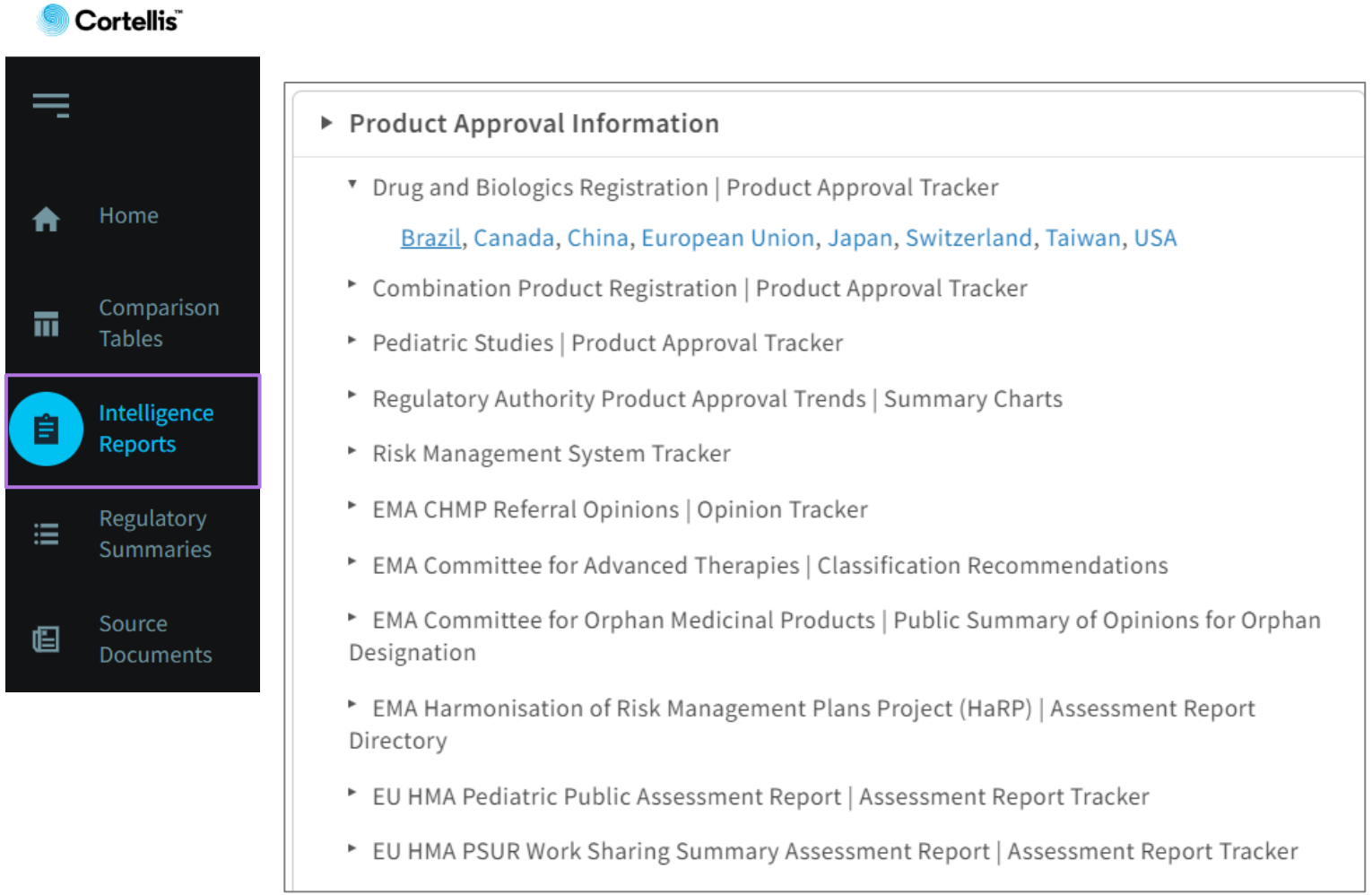

1.View at the top what type of translation is available for that document

2.Human Translations will be indicated by either Cortellis Translation, Authority Official or Authority Unofficial

3.The translation will be contained in the document with the native language version

# Assess the competition – find approved drugs for thousands of indications globally

## Product Approval Trackers – Brazil, Canada, China, EU, Japan, Switzerland, Taiwan and USA



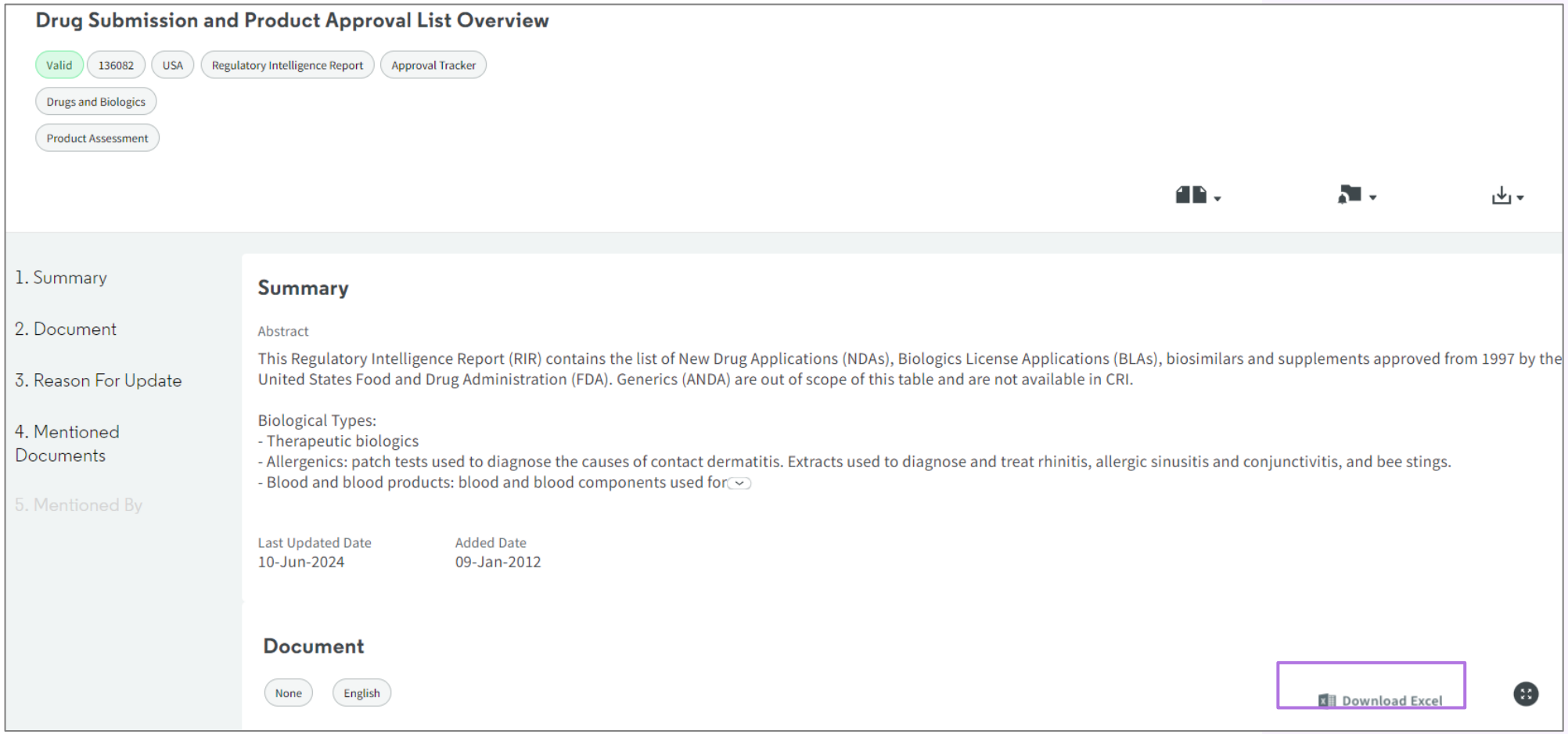

1.Go to the Regulatory Intelligence Reports

2. Scroll down to Product Approval Information

3. Click the country link to open the tables

# Assess the competition – find approved drugs for thousands of indications globally

Product Approval Trackers cover Brazil, Canada, China, EU, Japan, Switzerland, Taiwan and USA

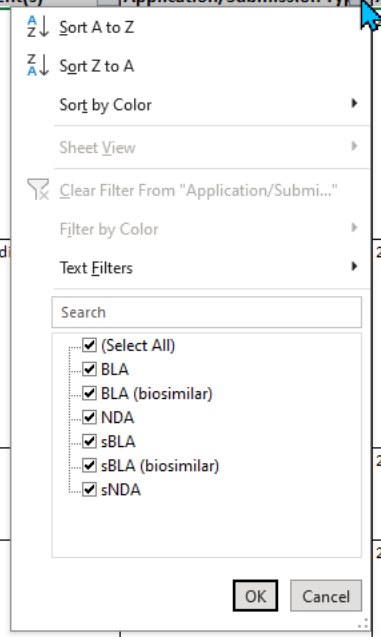



Click Download Excel to open the tables

# Assess the competition – find approved drugs for thousands of indications globally

## Product Approval Trackers – Brazil, Canada, China, EU, Japan, Switzerland, Taiwan and USA

| Name | Active Ingredient(s) | Application/Submission Ty | Application Numb | Active Substance Statu | FDA Biological Type | FDA Chemical Type | Product Type | Dosage Forn | Route of Administratior | Therapeutic Area | Indication(s) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| RAYOS | prednisone | | 202020/013 | Known active substance | Not applicable | New dosage form | Drugs & Biologics | Tablet | Oral | Cancer ; Dermatological disorders ; Endocrine disorders ; Eye disorders ; Gastrointestinal disorders ; Hematologic diseases ; Immunological disorders ; Infections ; Musculoskeletal and connective tissue disorders ; Neurological disorders ; | For the treatment of the following conditions: Allergic Conditions, De Diseases, Endocrine Conditions, G Diseases, Hematologic Diseases, N Conditions, Nervous System Condit Conditions, Conditions Related to Transplantation, Pulmonary Disea Conditions, Rheumatologic Condit Infectious Diseases. |
| ORAPRED ODT | prednisolone sodi | | 21959/014 | Known active substance | Not applicable | New dosage form | Drugs & Biologics | Tablet | Oral | Cancer ; Dermatological disorders ; Endocrine disorders ; Eye disorders ; Gastrointestinal disorders ; Hematologic diseases ; Neurological disorders ; Other disorders (systemic disorders) ; Respiratory disorders | In the following diseases or condit conditions, Dermatologic Diseases Conditions, Gastrointestinal Disea Diseases, Neoplastic conditions, N conditions, Ophthalmic conditions related to organ transplantation, P Diseases, Renal conditions, Rheum Conditions and Specific Infectious |
| HEMADY | dexamethasone | | 211379/006 | Known active substance | Not applicable | New combination ; New formulation or new manufacturer | Drugs & Biologics | Tablet | Oral | Cancer | In combination with other anti-my the treatment of adults with multip |
| CALQUENCE | acalabrutinib | | 210259/010 | New active substance | Not applicable | New molecular entity (NME) | Drugs & Biologics | Capsule | Oral | Cancer | CALQUENCE is indicated:<br>- For the treatment of adult patient lymphoma (MCL) who have receive therapy.<br>- For the treatment of adult patient lymphocytic leukemia (CLL) or sma lymphoma (SLL). |




Filter the tables by Therapeutic area, Application/Submission type and more

# Assess the competition – find approved drugs for thousands of indications globally

## Product Approval Trackers – Brazil, Canada, China, EU, Japan, Switzerland, Taiwan and USA

| Company | Legal Basis | Submission Date | Receipt Date | Advisory Committee Meeting Dat | Review Cycles | Approval Dat | Review Type | Orphan Designation | Orphan Designation Dat | Priority Review Vouche | Approval Type | Review Center | Review Off |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Horizon Therapeutics USA Inc. | 505(b) | 08-Mar-2024 | 08-Mar-2024 | | Not available | 05-Jun-2024 | Standard review | No | | No | No | CDER | Immunology New drugs |
| Concordia Pharmaceuticals Inc. | 505(b) | 01-Mar-2024 | 01-Mar-2024 | | Not available | 05-Jun-2024 | Standard review | No | | No | No | CDER | Immunology New drugs |
| Dexcel Pharma Technologies Ltd. | 505(b) | 22-Feb-2024 | 22-Feb-2024 | | Not available | 05-Jun-2024 | Standard review | No | | No | No | CDER | Oncologic D |
| AstraZeneca UK Ltd. | 505(b) | 23-May-2024 | 23-May-2024 | | Not available | 05-Jun-2024 | Standard review | No | | No | No | CDER | New drugs ; |

Compare Submission Dates and Approval Dates to understand how long approvals are taking and filter to Regulatory Designations

# Assess the competition – find approved drugs for thousands of indications globally

## Product Approval Trackers – Brazil, Canada, China, EU, Japan, Switzerland, Taiwan and USA

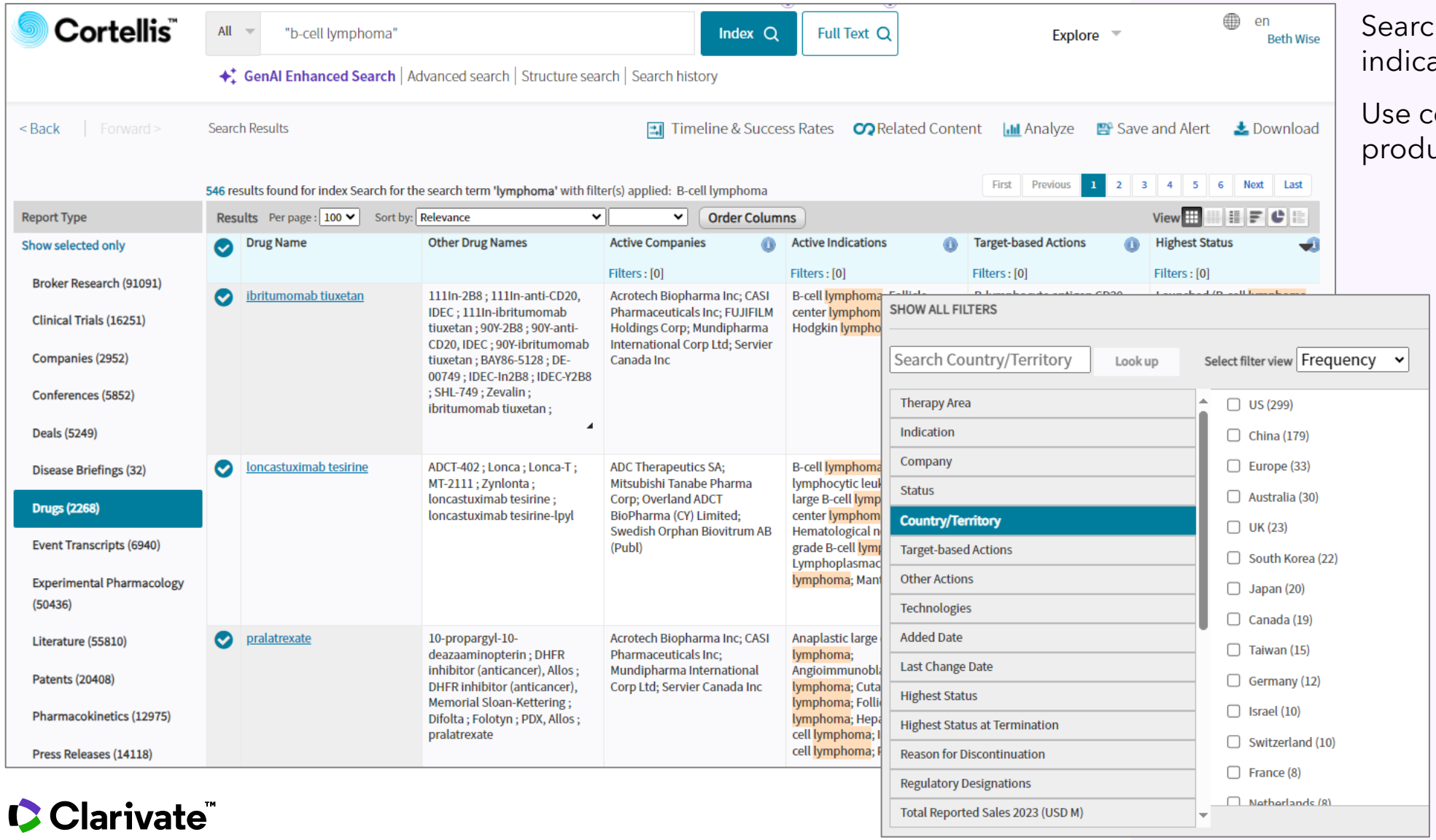
| Review Category/Division | Boxed Warni | Medication Guide | REMS | Pediatric Us | FDA Supplement Type | FDA Supplement Rationale | Link to Product Approval Document |
|---|---|---|---|---|---|---|---|
| Rheumatology and transplant medicine | No | No | No | Yes | Non-efficacy supplement | Provided for revisions to the labeling consistent with new safety information that pertains to the risk of activation of latent infections and special pathogens, and of Kaposi's sarcoma. | 385085 |
| Rheumatology and transplant medicine | No | No | No | Yes | Non-efficacy supplement | Provided for revisions to the labeling consistent with new safety information that pertains to the risk of activation of latent infections and special pathogens, and Kaposi's sarcoma. | 385068 |
| Not available | No | No | No | No | Non-efficacy supplement | Provided for revisions to the labeling consistent with new safety information that pertains to the risk of activation of latent infections and special pathogens, and Kaposi's sarcoma. | 385058 |
| Not available | No | No | No | No | Non-efficacy supplement | Provided for revisions to the labeling with agreed upon changes to the text consistent with the new safety information pertaining to the risk of cardiac arrhythmia including ventricular arrhythmia under Highlights of Prescribing Information, 5.5 Cardiac Arrhythmias, 5.6 Hepatotoxicity, Including Drug-Induced Liver Injury, 6.2 Postmarketing Experience, 17 Patient Counseling Information sections and Patient Package Insert. | 385051 |

Filter to find products with Boxed Warnings, Med Guides and REMS

Click the links to view the Approval Documents

# Assess the competition – find approved drugs for thousands of indications globally

## Cortellis Competitive Intelligence

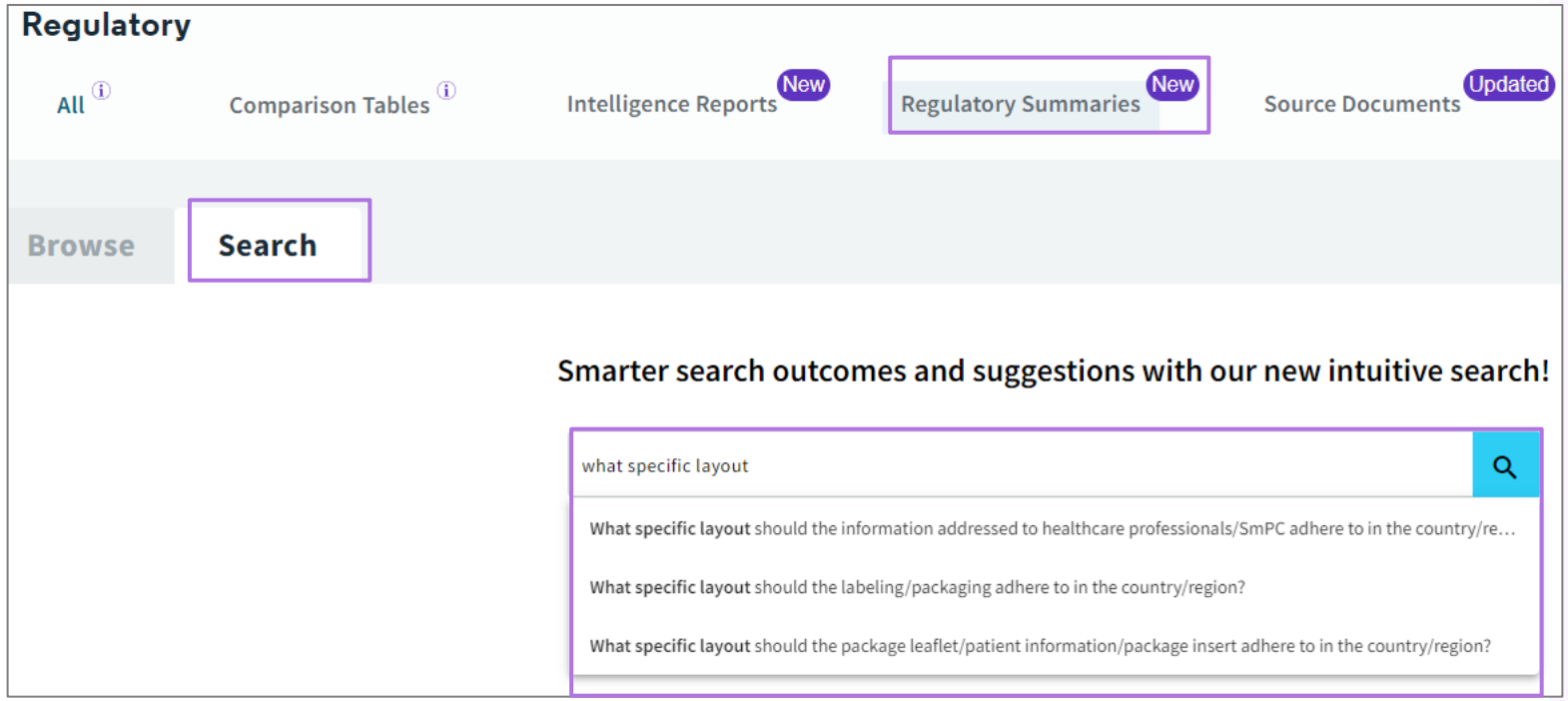



Search on over 2,000 global indications

Use country filters to find products globally

# New - Summary Intuitive Search

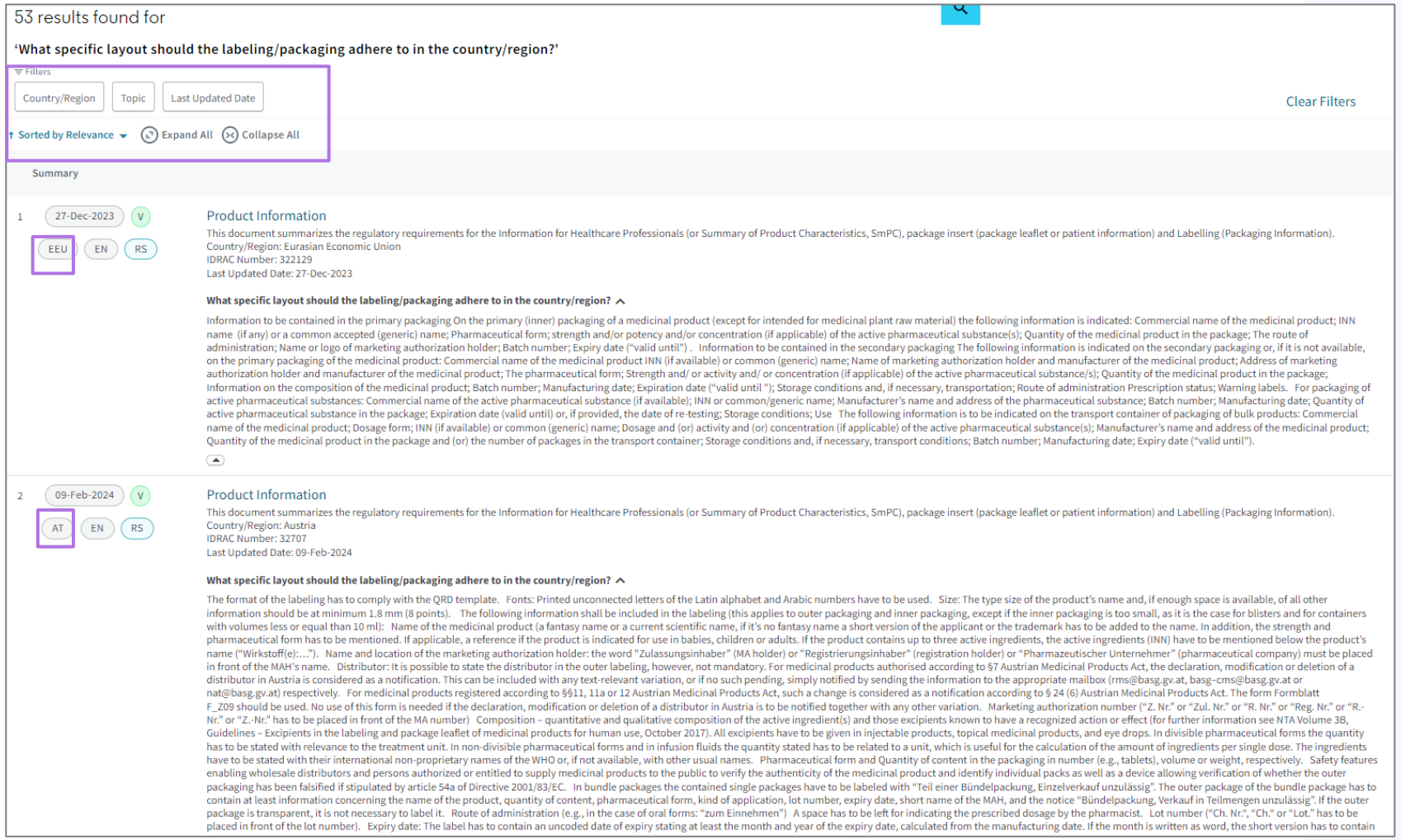
Search across countries on questions in the Summaries




1. Click Summaries
2. Click Search
3. Start typing in a question from the Summaries
4. Select question from the drop-down

# New - Summary Intuitive Search

## Search across countries on questions in the Summaries




1. Us filters to narrow down, e.g.; use My Country Filter under Countries/Region
2. Click Expand all to view answers on the page
3. View Countries on the left

# Feedback poll/Wrap-up

## What did I learn that will support me the most in my role?

1. *Running searches and setting up alerts* – track US and EU labels by drug, disease, regulatory designation and more
2. *Comparison Tables* - compare packaging and labelling requirements on 80+ countries, for example, are Mandatory Warnings or Braille language required?
3. *Regulatory Summaries* - curated reports providing the guidance I need on labeling policy
4. *Human and machine English translations* – available for every valid source document
5. *Access the competition* – find approved drugs for thousands of indications globally

## My additional feedback on Cortellis/today's training is:

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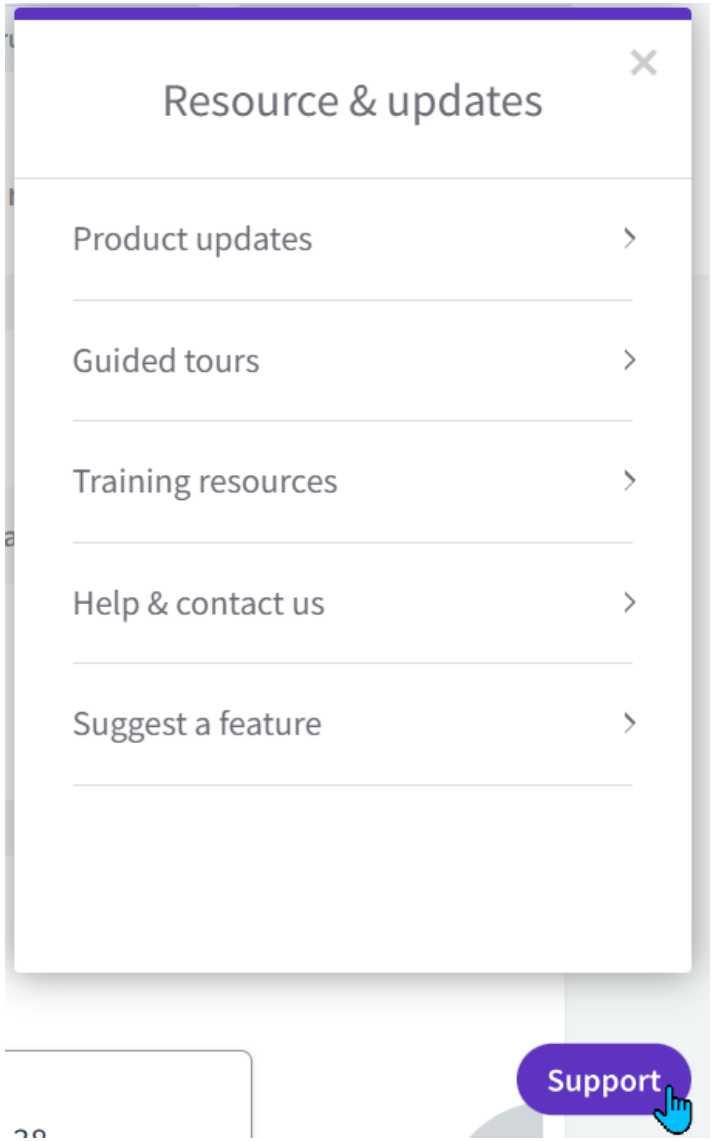
# Get assistance with Cortellis

## In-product guidance to assist you with your questions

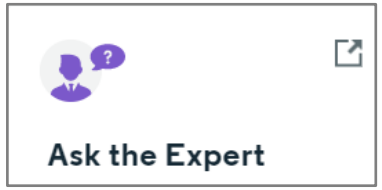
- Click at the question mark at the bottom of the screen

If not visible, please enable functional cookies under "Manage cookie preferences".

Manage cookie preferences




- Help & contact us – contact Customer Care
- Guided tours – walk through the Cortellis platform
- Training resources – recorded trainings, Quick guides and short videos
- Ask the Expert (on Regulatory homepage)

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